The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE CTI BIOPHARMA CORP. SECURITIES LITIGATION	Case No. 2:16-cv-00216-RSL Hon. Robert S. Lasnik **CLASS ACTION** **JURY TRIAL DEMANDED**

CONSOLIDATED CLASS ACTION COMPLAINT

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GLOSSARY OF TERMS

ASCO:	American Society of Clinical Oncology.
BAT:	Best Alternative Therapy, which serves as a comparator to the drug being tested in clinical studies.
Bianco:	James Bianco, CTI founder and long-time president and CEO.
Class Period:	March 9, 2015, through February 9, 2016, inclusive.
Clinical hold:	An order by the FDA to the drug sponsor to terminate drug studies.
Comparative study:	A clinical study in which the study-drug's safety and efficacy is compared against alternative therapies or placebo.
Crossover:	Switching from one arm of a clinical trial to another arm; in this case, "crossover" typically refers to the patient crossing over from the best-available-therapy arm used in the clinical trial to the pacritinib arm.
CTI or the Company:	CTI BioPharma Corp., f/k/a Cell Therapeutics Inc.
December 2015 Offering:	The offering by CTI completed in December 2015 conducted pursuant to a shelf registration statement and prospectus dated November 21, 2014, filed with the SEC on Form S-3.
Exchange Act:	Securities Exchange Act of 1934, 15 U.S.C. §78a, et seq.
FDA:	U.S. Food and Drug Administration.
FOIA:	Freedom of Information Act, 5 U.S.C. § 552.
IDMC or DMC:	Independent Data Monitoring Committee or Data Monitoring Committee. A committee that oversees clinical trials and reviews clinical data on an ongoing basis to ensure the safety of patients participating in the trial. Based on these reviews, they recommend to the sponsor whether or not to continue administering an experimental drug to the patients. With respect to pacritinib, it is referred to as the IDMC.
Lead Plaintiff or DAFNA:	DAFNA LifeScience, LP and DAFNA LifeScience Select, LP.
Myelofibrosis:	A blood-related cancer that annually affects roughly 3,500 people in the U.S.

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NDA:	A New Drug Application filed with the FDA for the approval of a new drug.
October 2015 Offering:	The offering by CTI completed in October 2015 conducted pursuant to a shelf registration statement and prospectus dated November 21, 2014, filed with the SEC on Form S-3.
Offering Materials:	With respect to a particular Offering (either the October 2015 Offering or the December 2015 Offering), the registration statement and prospectus, together with the applicable prospectus supplements, as well as all SEC filings incorporated therein.
PAC:	Pacritinib. When "PAC arm" is referenced herein, it means the portion of the study in which patients are given pacritinib.
PERSIST trials:	Two phase 3 trials designed for the study of pacritinib as a drug to treat myelofibrosis.
Phases of clinical trials:	Refers to the phases of a clinical research for the FDA to approve a new drug product. Phase 1 study objectives focus on the dosage and provides early information on safety in healthy humans. Phase 1 is intended to provide enough information to permit the design of a well-controlled scientifically valid Phase 2 study. The Phase 2 objectives include determining the safety and effectiveness of the dose in patients with the target disease, and, among other things, identifies short-term adverse effects. Phase 2 is intended to provide enough information to permit the design of well-controlled scientifically valid Phase 3 studies. The Phase 3 objectives include determining the safety and effectiveness in a large population of the tested drug and an alternative (best available therapy or placebo, etc.). Phase 3 is intended to confirm information about safety and effectiveness of dose administration and identify drug-related adverse events/reactions, precautions, and drug interactions.
Plaintiffs:	Lead Plaintiff DAFNA and named plaintiff, Michael Li.
SEC:	U.S. Securities and Exchange Commission.
Securities Act:	Securities Act of 1933, codified at 15 U.S.C. §77a, et seq.
Splenomegaly:	A medical condition involving spleen enlargement.
Thrombocytopenia:	A medical condition involving a reduction in platelet count.

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Court-appointed Lead Plaintiff, DAFNA LifeScience, LP and DAFNA LifeScience Select, LP ("DAFNA" or "Lead Plaintiff"), asserts claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "Securities Act") individually and on behalf of all persons and entities, except Defendants and their affiliates as more particularly defined below, who purchased or otherwise acquired CTI BioPharma Corp. ("CTI" or the "Company") securities pursuant or traceable to CTI's October and December 2015 Offerings, and were damaged thereby.

Separately, Lead Plaintiff and additional plaintiff Michael Li (collectively, "Plaintiffs") assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") individually and on behalf of all persons and entities who purchased or otherwise acquired CTI securities between March 9, 2015, through February 9, 2016, inclusive (the "Class Period"), and were damaged thereby (the "Class"). Defendants, and certain other persons and entities as more particularly defined below, are excluded from the Class.

Plaintiffs' allegations are based upon personal knowledge as to themselves and their actions, and upon Lead Counsel's investigation as to all other matters. Such investigation included review and analysis of: (i) CTI's public filings with the Securities and Exchange Commission (the "SEC"); (ii) research reports by securities and financial analysts; (iii) transcripts of CTI's conference calls with analysts and investors; (iv) presentations, press releases, and reports; (v) news and media reports concerning the Company; (vi) data reflecting the pricing of CTI securities; (vii) consultations with relevant experts; and (viii) other material and data concerning the Company. Counsel's investigation into the factual allegations continues, and many of the relevant facts are known only by the Defendants or are exclusively within their custody or control. Plaintiffs believe that substantial additional evidentiary support is likely to exist for the allegations set forth herein after a reasonable opportunity for further investigation or discovery.

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I. INTRODUCTION

1. CTI is a biopharmaceutical company. Throughout the Class Period, CTI's President and Founder, Dr. James Bianco, focused investor attention on CTI's "lead drug candidate," pacritinib, which was promoted as a safe drug treatment for myelofibrosis with "blockbuster" potential. The FDA's decision whether to approve the drug (and to allow for its marketing and sale) hinged on the safety results of two Phase 3 clinical trials, known as the "PERSIST trials." The PERSIST trials were "comparative trials," meaning that patients were divided into two study groups – those who received pacritinib and those who received an alternative therapy – and the number of serious adverse events (*e.g.*, deaths, cardiac arrests) were compared between the two study groups.

2. As is customary, the PERSIST trials were overseen by an independent data monitoring committee, known as the "IDMC." Pharmaceutical companies have utilized data monitoring committees to oversee Phase 3 clinical trials for decades. These committees, which are comprised of three or more trained clinicians and biostatisticians appointed by the drug sponsor, review the critical Phase 3 clinical data on an ongoing basis and provide interim safety updates and, ultimately, a recommendation to the company about the study. As the FDA has explained, "[m]ost frequently, a [data monitoring committee]'s recommendation after an interim review is for the study to continue as designed." In the rare event that the data monitoring committee recommends terminating the study due to a safety concern, drug companies routinely adhere to the recommendation, disclose the recommendation, and terminate the study.

3. In reviewing results of comparative trials, both the FDA and data monitoring committees focus on the number of severe adverse events that patients experience in the two comparative trial groups – *i.e.*, whether a higher amount of patients that received the experimental drug die, suffer heart attacks, or report other serious adverse events. As explained by Richard A. Guarino, MD, an expert on the FDA's standards and regulations for the drug approval process, the FDA focuses on whether there is an imbalance in the number of deaths or

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other serious adverse effects between the two comparative trial groups when it evaluates the clinical research results of a new drug. When there is an imbalance in deaths or other serious adverse events between the two study arms, the FDA will impose a "clinical hold" on the studies and, thus, the drug will not be approved for current marketing or sale. For this reason, investors also pay close attention to the information that is disclosed by drug companies about the number and types of serious adverse events in the different arms of clinical trials, such as the PERSIST trials.

4. During the Class Period, CTI and Defendant Bianco repeatedly described the purportedly "positive" results of the "very pivotal" PERSIST-1 trial. The Company's SEC filings, press releases, and investor conferences each emphasized how pacritinib's safety profile in the PERSIST-1 trial "was consistent with prior Phase 2 trials," which they had said "demonstrated the safety, tolerability and persistence of pacritinib." CTI and Bianco further described the supposedly limited adverse events observed in the PERSIST-1 trial, stating that "the incidence of grade 3 [adverse] events was lower than observed in Phase 2 trials" and that "very few" – only "[t]hree patients" – "discontinued therapy" while on pacritinib. In turn, investors and financial analysts singled out the drug's "safety" and the results of the PERSIST-1 trials as reasons to buy the Company's stock.

5. CTI further assured investors that the PERSIST-1 trial data showed an identical percentage of deaths between the two arms of the PERSIST-1 trials. For example, on May 30, 2015, CTI's 24-week PERSIST-1 trial data was presented at the 2015 American Society of Clinical Oncology. During that presentation, investors were told that an identical percentage of just 1% of patients in both study arms had died. This was important to investors because, as noted above, when an imbalance exists in the number of deaths or other serious adverse events between two study arms, the FDA will impose a clinical hold on the studies.

6. CTI also assured investors by identifying the involvement of the IDMC in its study protocol filed with the FDA, as well as in its SEC public reports signed by Defendant

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Bianco that purported to describe the IDMC's findings and recommendations. As the FDA has explained, the participation of an independent data monitoring committee "increases the credibility of the trial's conclusions."

7. On the heels of CTI's positive disclosures about pacritinib's "safety," CTI and Bianco offered millions of new shares of CTI common stock to investors through offerings of preferred shares that automatically converted to common stock. In the Offering Materials that CTI provided to these investors, CTI again described the purported conclusions of the IDMC and results of the PERIST-1 studies. Through these representations, CTI secured over $100 million from investors, including Lead Plaintiff DAFNA.

8. As investors would ultimately learn, however, the IDMC's findings and recommendations, as well as the results of the PERSIST-1 study, were far different than publicly reported during the Class Period. In truth, the IDMC had recommended as early as February 2015 that CTI "***terminate*** the PERSIST-1 trial and ***hold enrollment*** of new patients in the PERSIST-2 trial." Further, the IDMC's recommendation to stop the trials was based on "safety concerns, ***including mortality***." Despite the IDMC's recommendation, Defendants Bianco and CTI took the unprecedented step of proceeding forward with their trials without disclosure, and misleading investors about the IDMC's findings and recommendations.

9. Investors would also come to learn that the results of the PERSIST-1 studies were different than represented by Defendant Bianco and the Company. As noted above, the FDA shuts down clinical trials when there is an imbalance in the percentage of deaths or severe cardiac events between the drug-arm and the alternative therapy-arm of a clinical trial. The 24-week results of the PERSIST-1 study, which the Company had at the start of the Class Period, showed such an imbalance, with nearly twice the percentage of patients given pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance in the percentages of patients suffering severe cardiac events.

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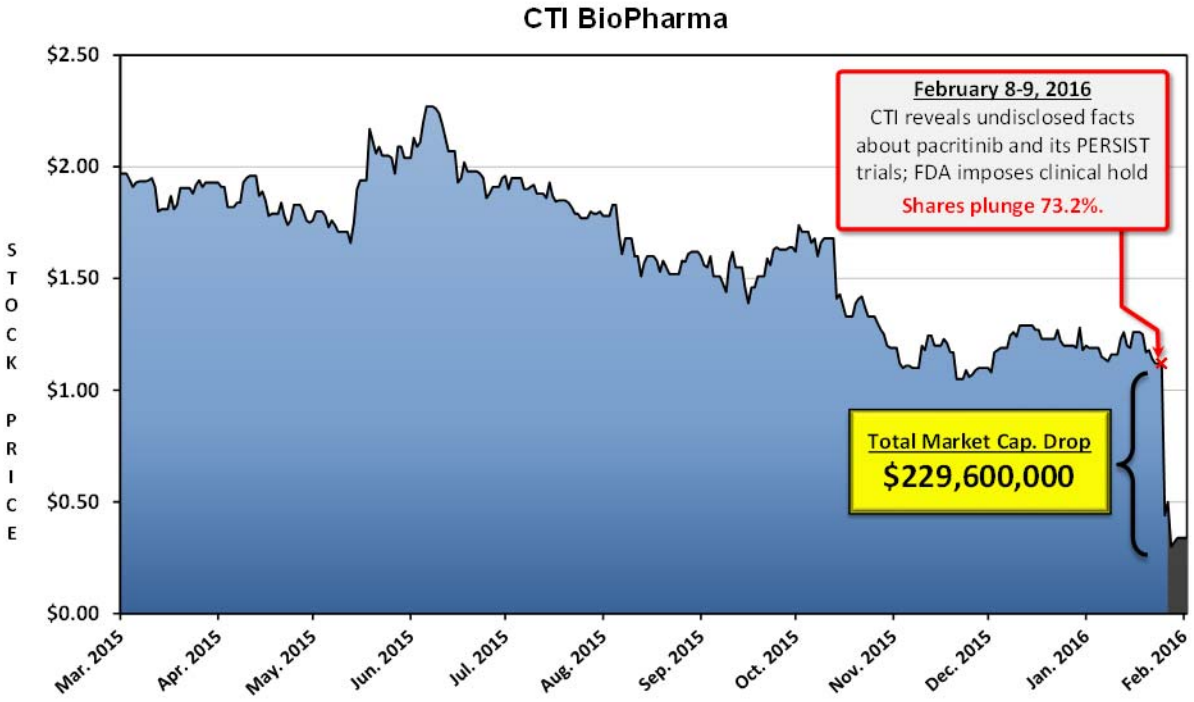
10. After its review of the true PERSIST trial data showing this imbalance, the FDA ordered a hold on the PERSIST studies. In stopping the studies, the FDA explained that "there was excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial" and that the PERSIST trials showed "a detrimental effect on survival" – just like the IDMC found a year earlier. The FDA further highlighted how the deaths among participants in the pacritinib group included cardiac failure and cardiac arrest.

11. Securities analysts considered these revelations a "blowup," with the disclosures revealing "alarming safety problems." Analysts further concluded that "the chance [that] CTI Bio resurrects pacritinib are slim to none." In a matter of just two business days, CTI's stock price plummeted by 73.2%, wiping out $229.6 million in market capitalization, as shown below:



12. In the aftermath, CTI has now admitted that the SEC had been conducting an investigation into the Company's violations of the securities laws even before the FDA stopped the PERSIST studies. The SEC's investigation focused on the pacritinib Phase 3 trials and the

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Company's communications with the IDMC. In the midst of the SEC's investigation, which remains ongoing, CTI recently announced Bianco's unexpected and immediate "resignation."

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13. This Complaint is divided into two, separate parts. In the first part, Lead Plaintiff asserts claims for violations of the Securities Act of 1933, which imposes strict liability for misstatements and omissions in offering documents for newly-issued securities. For such claims, Lead Plaintiff does not need to allege, and does not allege, that Defendants acted with scienter.

14. In the second part of the Complaint, Plaintiffs assert claims against CTI and Defendant Bianco for violations of the Exchange Act of 1934, which imposes liability for additional misstatements and omissions that were made with scienter.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and Section 22 of the Securities Act, 15 U.S.C. § 77v. In addition, because this is a civil action arising under the laws of the United States, this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions that constitute violations of law complained of herein, including the dissemination to the public of untrue statements of material facts, occurred in this District.

17. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of a national securities exchange.

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SECURITIES ACT CLAIMS

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SECURITIES ACT CLAIMS

18. The Securities Act holds signatories of registration statements, among others, strictly liable for untrue statements and omissions of material fact in certain documents provided to investors in connection with securities offerings. Claims brought under the Securities Act do not require a showing of fraud, scienter, reliance, or causation. In asserting claims under the Securities Act, Lead Plaintiff does not allege, and specifically disclaims, any allegations of fraud or intent.[1]

A. Securities Act Parties

1. Securities Act Plaintiffs

19. On September 2, 2016, the Court appointed DAFNA as Lead Plaintiff. As set forth in the accompanying certification, DAFNA purchased CTI securities pursuant or traceable to the Offerings during the Class Period and suffered damages as a result of the violations of federal securities laws alleged herein.

2. Securities Act Defendants

a) Corporate Defendant

20. Defendant CTI BioPharma Corp. is a biopharmaceutical corporation located in Seattle, Washington. The Company's common stock trades under the ticker symbol "CTIC" on the NASDAQ stock exchange and on the Mercato Telematico Azionario ("MTA") in Italy. As of October 31, 2016, there were over 280 million shares of CTI common stock outstanding. Defendant CTI is named in Count I (Section 11) and Count II (Section 12(a)(2)) of the Securities Act claims.

[1] The substantive allegations of the Securities Act section of this Complaint stand alone. The Securities Act section of the Complaint does not incorporate any allegations in the Exchange Act section of the Complaint (paragraphs 103-192) or the introduction to the Complaint (paragraphs 1-12).

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b) Defendant James A. Bianco

21. Defendant James A. Bianco was the principal founder, CEO and President of CTI. Defendant Bianco signed each of the Company's registration statements and quarterly and annual reports incorporated therein, which contained the false and misleading statements and omitted material facts discussed below. Defendant Bianco is named in Count I (Section 11) and Count III (Section 15) of the Securities Act claims.

c) The Executive Signatory Defendants

22. The Securities Act imposes strict liability on company executives who sign registration statements for the offerings in which there were material misstatements or omissions in the offering documents. In addition to Defendant Bianco, the following CTI executive signed the registration statement for the Offerings and, accordingly, is liable under the Securities Act: Louis A. Bianco ("Louis Bianco"), who was CTI's Principal Financial Officer and Principal Accounting Officer at all relevant times. The Executive Signatory Defendants are named as Defendants for Count I (Section 11) of the Securities Act claims.

d) The Director Defendants

23. The Securities Act imposes strict liability on company directors who sign registration statements for offerings in which there were material misstatements or omissions in the offering documents. In addition to Defendant Bianco, each of the following CTI directors signed the registration statement for the Offerings and, accordingly, are liable under the Securities Act: Defendants Jack W. Singer ("Singer"), Frederick W. Telling ("Telling"), Reed V. Tuckson ("Tuckson"), Phillip M. Nudelman ("Nudelman"), John H. Bauer ("Bauer"), Karen Ignagni ("Ignagni"), Richard L. Love ("Love"), and Mary O. Mundinger ("Mundinger"). The Director Defendants are named in Count I (Section 11) of the Securities Act claims.

e) The Underwriter Defendants

24. The Securities Act imposes strict liability on underwriters of offerings in which there were material misstatements or omissions in the offering documents. The following

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investment banks were underwriters of the Offerings of CTI securities issued by way of a registration statement that contained materially untrue and misleading statements and omitted material facts: Piper Jaffray & Co. ("Piper Jaffray"), Ladenburg Thalmann & Co. Inc. ("Ladenburg Thalmann"), Roth Capital Partners, LLC ("Roth Capital"), and National Securities Corporation ("National Securities") (collectively, the "Underwriter Defendants"). Piper Jaffray and Ladenburg Thalmann were underwriters for both of the Offerings; National Securities was an underwriter in the October 2015 Offering; and Roth Capital was an underwriter in the December 2015 Offering. The Underwriter Defendants are named in Count I (Section 11) and Count II (Section 12(a)(2)) of the Securities Act claims.

B. Summary Of Factual Allegations For Securities Act Claims

1. Overview Of CTI And Its "Blockbuster" Drug Pacritinib

25. CTI is a biopharmaceutical drug company that was founded 25 years ago and has been controlled by its Chief Executive Officer and President, James A. Bianco. Pacritinib was the most prominent drug in CTI's pipeline during the Class Period. Defendant Bianco and CTI identified pacritinib as "the blockbuster [drug] for the company," its "lead development candidate" and its "foremost investigational agent."[2] In speaking with investors, Defendant Bianco "underscore[ed] the importance of [the] pacritinib program to the Company"[3] and repeatedly stated that it was an "attractive" and "very valuable asset for the Company."[4]

26. On November 15, 2013, CTI announced that it had entered into a licensing agreement with Baxter International Inc. ("Baxter") for the development and commercialization of pacritinib. Under the agreement, the two parties shared joint commercialization rights to pacritinib in the United States. The agreement called for an upfront payment to CTI of

[2] *See* https://www.youtube.com/watch?v=9_sdkfYs1hA (at :25); Q3 2013 Investor Call.

[3] CTI Conference Call Transcript dated April 29, 2014.

[4] Cell Therapeutics Transcript dated June 6, 2012.

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$60 million, as well as that Baxter make certain "milestone" payments to CTI related to successful achievement of certain development and commercialization accomplishments.[5]

27. Pacritinib was a once-a-day, oral drug that was supposed to safely treat myelofibrosis, which is a blood-related cancer that affects approximately 3,500 people annually in the U.S. alone.[6] Individuals suffering from myelofibrosis are unable to create normal blood cells from their bone marrow, which causes their blood cell production to move to their spleen. As a result, myelofibrosis patients often experience spleen enlargement, referred to as "splenomegaly." Other symptoms from myelofibrosis include anemia, as well as a reduction in platelet count, which is also referred to as "thrombocytopenia." Pacritinib was supposed to effectively and safely treat myelofibrosis by inhibiting the body's JAK2 receptors.

28. Financial analysts covering CTI's stock estimated that the market size for pacritinib exceeded $2 billion, and that CTI could garner annual sales of "at least $500 MM" from the drug.[7] These analysts further observed that "CTIC shares are materially dependent upon pacritinib success."[8] Analysts' valuations of the Company primarily focused on anticipated revenues from pacritinib, with analysts at Piper Jaffrey, for example, ascribing over 75% of the Company's net present value to anticipated revenues from sales of the drug.[9] Similarly, Ladenburg Thalmann ascribed approximately 50% of its CTI valuation to pacritinib, which also formed the basis for its "buy" rating for the stock. Other analysts such as Roth Capital similarly stated that CTI's entire future was likely to be determined by pacritinib.

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[5] CTI Press Release dated November 15, 2013.

[6] Alex Lash, *CTI Goes Up, And Down, And Back Up On Phase 3 Myelofibrosis News,* Xconomy Seattle, March 9, 2015.

[7] *See, e.g.*, H.C. Wainwright analyst reports published on August 5, 2014, October 30, 2014, March 13, 2015, and May 7, 2015.

[8] *See, e.g.*, Roth Capital Partner analyst reports May 14, 2014.

[9] *See* Piper Jaffray analyst report March 9, 2015.

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29. CTI and Defendant Bianco touted pacritinib as safer and more effective than the best alternative therapies, including its main drug rival in the field – a drug called Jakafi produced by the company Incyte. According to Bianco, the FDA did not approve Jakafi for patients with low platelet counts. Defendant Bianco and CTI stressed to investors that Jakafi's purportedly limited FDA approval presented a market opportunity for CTI. Specifically, Defendant Bianco and CTI told investors that pacritinib's use for patients with low platelet counts provided it with "a differentiated efficacy and safety profile" that would "fill a gap that exists for many patients whose lives are profoundly impacted by myelofibrosis, particularly those patients with low platelet counts."[10] It was thus especially important to investors that pacritinib – which had not yet been approved by the FDA – demonstrate that it was safer than the alternative therapies.

2. The FDA Approval Process

30. As explained by Dr. Guarino, an expert in the FDA approval process, no drug may be approved for sale in the United States unless the FDA determines that it can be safely and effectively prescribed to patients for its intended use.[11] To obtain FDA approval, drug companies are required to prepare a new drug application, conduct clinical trials and, when the trials are completed, send the study results to the FDA for its review. If the clinical trial results show that the drug is safe and effective, the FDA is likely to approve the drug. Conversely, if the clinical

[10] CTI Press Release dated December 5, 2015.

[11] Dr. Guarino is an expert on the FDA's standards and regulations for the drug approval process, as well as marketing and promotion related to the sale of drugs in the United States. He has worked in the pharmaceutical industry for over 40 years. Over the course of his career, he has played numerous roles in clinical research development and marketing of drugs sold in the United States and globally. He is intimately familiar with regulations promulgated by the FDA. He has advised pharmaceutical companies on the FDA regulatory processes, including the regulations and guidelines promulgated by the FDA and the International Committee on Harmonization concerning how drug-related clinical research and marketing of drugs must be conducted. Among other things, since 1987, Dr. Guarino has authored multiple editions of the book entitled "New Drug Approval Process: Clinical and Regulatory Management" (Marcel Dekker, Inc. 1987), which is used as a text and guide by the pharmaceutical industry and medical schools.

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trial results show that the drug is unsafe or ineffective, the FDA will not approve the drug and will place a hold on additional clinical trials.

31. There are typically three phases of clinical trials for drugs that are not yet approved by the FDA. The results of the third phase – known as "Phase 3 trials" – are the most important to the FDA and, accordingly, to investors. This is because, as the FDA has explained, "Phase 3 studies provide most of the safety data" and "[i]n previous studies, it is possible that less common side effects might have gone undetected."[12]

32. Phase 3 trials are often "comparative studies," in which the study-drug's safety and efficacy is compared against alternative therapies. A primary purpose of a Phase 3 comparative study is to determine whether there is a difference in the rate of serious adverse events among patients who receive the drug being tested and those given the alternative therapies.

33. The FDA will not approve a drug for sale, and instead will impose a clinical hold, when there is an imbalance in deaths or serious adverse events between the group of patients taking the drug being studied and the group of patients receiving the alternative therapies. As detailed in Dr. Boudes' comprehensive study, *An Analysis of U.S. Food and Drug Administration Clinical Hold Orders for Drugs and Biologics*, clinical holds are "mostly motivated by a safety concern and, particularly, by a clinical safety issue."[13] The most frequent reason for an FDA clinical hold order is one or more deaths and, thus, "logically, an unexpected death or an excess of deaths constitute highest risk for a clinical hold order."[14] As David Gortler, a former FDA senior medical officer and drug-safety expert and consultant, explained to *The Seattle Times* in a

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[12] http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.

[13] Pol F. Boudes, MD, PhD, *An Analysis of U.S. Food and Drug Administration Clinical Hold Orders for Drugs and Biologics: A Prospective Study Between 2008 and 2014*, Pharm. Med. (2015) Vol. 29:203. Dr. Boudes has experience as a Chief Medical Officer and in other positions at various therapeutics companies. He previously practiced medicine and held academic appointments at hospitals.

[14] Boudes, *supra*.

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February 2016 interview concerning the PERSIST-1 studies, "[p]atient deaths are a rare occurrence, generally speaking, within clinical trials . . . Even one death is cause enough to shut down a clinical trial."[15]

34. The FDA has made clear that it will order a clinical hold, and not approve a drug application, when there is an imbalance in the percentage of patients dying or suffering serious adverse events between the drug and control arm of a study. For example, in 2008, the FDA put a clinical hold on the phase III trial of GVAX, a drug aimed at treating prostate cancer, due to an imbalance in deaths between the study-drug group and the control group. Also in 2008, the FDA placed a clinical hold on the study of Alvimopan due to an observed imbalance in cardiovascular events. In 2009, the FDA halted the clinical trials of Elesclomol, a drug for the treatment of melanoma, due to an imbalance of deaths between those taking the study-drug and those taking alternate treatments. And, as another example, in 2010 the FDA halted the clinical trial for GlaxoSmithKline's TIDE drug trials for Avandia, which targeted Type 2 diabetes, due to an observed imbalance in cardiovascular events between the drug and control arm. As Dr. Guarino has explained, "it is generally understood in the industry that the FDA will impose a clinical hold whenever there is an unfavorable imbalance in deaths or severe cardiac events between the drug and control arm of a study; an FDA hold in such situations is not only likely, it is a certainty."

3. The PERSIST-1 Study

35. In January 2013, CTI began its pivotal PERSIST-1 clinical trial, which CTI described as a Phase 3 study to test the "efficacy and safety" of pacritinib.[16] The PERSIST-1

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[15] Rachel Lerman, *FDA halts trial of cancer drug by Seattle's CTI BioPharma after patients die*, The Seattle Times, Feb. 11, 2016, http://www.seattletimes.com/business/fda-halts-cti-biopharma-drug-trial-for-detrimental-effect-on-survival/. David Gortler, PharmD, FCCP, served on a federal level as a medical officer for the FDA, where he advised and lead a team of professional FDA experts on applications and queries from drug companies. He served as an FDA front-line contact directly to drug companies applying for new-drug approvals and labeling supplements. He was previously a Senior Medical Analyst and Medical Officer in the Division of Metabolism and Endocrinology at the FDA in the Office of New Drugs.

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study was a comparative study, with the participants receiving either pacritinib (the "PAC arm") or the best alternative therapy (the "BAT arm"). It was a randomized 2:1 study, meaning that approximately two-thirds of the 327 patients enrolled in the study received pacritinib (and, thus, were in the PAC arm) and one-third of the patients received the best alternative therapy (and, thus, were in the BAT arm).[17] The study was limited to patients expected to live longer than at least 6 months, and excluded anyone who suffered from a cardiovascular disease.[18]

36. The safety results from the Phase 3 PERSIST-1 study were important to CTI's stock price. CTI stated in its SEC filings that the PERSIST-1 study was the Company's "pivotal Phase 3 trial of pacritinib," and Defendant Bianco referred to the PERSIST-1 study as a "very big pivotal outcome" for the Company.[19] Additionally, in its Form 10-K filed March 12, 2015, CTI stated under "Item 1. Business, Overview" that one of the two business items it was "primarily focused on" in 2015 was "conducting a Phase 3 clinical trial program of pacritinib." Securities analysts likewise appreciated the significance of the PERSIST-1 study, with analysts at Ladenburg Thalmann, for example, reporting that it "would be very positive" if the PERSIST-1 results comported with CTI's Phase II trials, which the Company had said showed no safety concerns.[20]

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[16] *See, e.g.*, Cell Therapeutics Press Release dated January 9, 2013.

[17] Patients were allowed to "crossover" from the BAT arm to the PAC arm after 24 weeks or upon disease progression prior to week 24. CTI Press Release dated March 9, 2015.

[18] Pacritinib PERSIST study protocol.

[19] *See, e.g.*, CTI Press Release dated October 29, 2014, attached to its SEC Form 8-K; *see also A Conversation with CTI's James Bianco, Part I*, Puget Sound Business Journal, Aug. 31, 2012 http://www.bizjournals.com/seattle/news/2012/08/31/a-conversation-with-ctis-jim-bianco.html.

[20] Ladenburg Thalmann Analyst Reports, including dated March 13, 2015.

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4. CTI Misleads Investors About The Results Of PERSIST-1 And Pacritinib's "Safety Profile"

37. Beginning in March 2014, CTI told investors through a series of SEC filings about the "positive" results for the PERSIST-1 study, which provided assurances about the "safety profile of the drug." According to the Company's filings, "[t]he safety profile in the [PERSIST-1] trial was consistent with prior Phase 2 trials," and "the incidence of grade 3 events was lower than observed in Phase 2 trials."[21] The Phase 2 safety trials, meanwhile, had been previously heralded by the Company in its SEC filings and elsewhere as successful in demonstrating the "safety, tolerability and persistence of pacritinib."[22] As the Company explained, the Phase 2 safety trials showed that "[e]ven patients with initial platelet counts of less than 50,000, a high risk population, tolerated therapy and maintained stable blood and platelet counts, and did not require dose reduction of thrombocytopenia."[23]

38. The Company's Class Period SEC filings also discussed the supposedly limited adverse events suffered by patients treated with pacritinib during PERSIST-1, stating, among other things, that "the incidence of grade 3 events was lower than observed in Phase 2 trials" and that "very few patients discontinued treatment while on pacritinib or required a dose reduction."[24] The Company's SEC filings also purported to disclose detailed information about the adverse events observed, noting for example that "[g]astrointestinal symptoms were the most

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[21] CTI SEC Form 10-K filed March 12, 2015.

[22] *See, e.g.*, Cell Therapeutics Press Release dated July 31, 2013 (under heading "New Data Presentation on Pacritinib's Safety Profile": "Reported results from pooled integrated safety analysis from four Phase 1 and 2 clinical studies that demonstrated the safety, tolerability and persistence of pacritinib, CTI's novel, oral JAK2/FLT3 inhibitor, in patients with myelofibrosis at the European Hematology Association Congress.")

[23] Q3 2013 Cell Therapeutics, Inc. Earnings Conference Call Transcript dated October 30, 2013.

[24] CTI SEC Form 10-K filed March 12, 2015.

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common adverse events and typically lasted for approximately one week" and that "[t]here were no Grade 4 gastrointestinal events reported."[25]

39. In October and December 2015, CTI issued over $100 million in new shares. In selling these new shares, the Company prepared "Offering Materials," which consisted of the registration statement, prospectuses, and prospectus supplements. The prospectus supplements purported to describe the results of the PERSIST-1 trial, including how only a "limited number of patients discontinued treatment due to side effects," and that the "data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor)[,] pacritinib therapy resulted in a significantly higher proportion of patients with … control of disease-related symptoms."[26] The Offering Materials also specifically incorporated by reference the 2015 SEC filings discussed below in paragraphs 66-67 and 73, including their purported description of the PERSIST-1 safety results and how "very few patients discontinued treatment while on pacritinib or required a dose reduction."[27]

40. Analysts and investors responded favorably to the Offering Materials. After CTI issued its October 2015 Prospectus Supplement, financial analysts at Ladenburg Thalmann reiterated their "buy" recommendation, highlighting the purportedly positive data from the pacritinib studies.[28] Likewise, shortly after the issuance of the December 2015 Prospectus Supplement, financial analysts at Piper Jaffray repeated that "side effects from pacritinib appear to be mild, most commonly involving transient [gastrointestinal] symptoms, and the company has presented analyses demonstrating improved patient reported outcomes and [quality of life]

[25] CTI SEC Forms 10-Q filed August 6, 2015 and November 5, 2015.

[26] CTI Prospectus Supplements dated October 27, 2015, and December 4, 2015.

[27] CTI SEC Form 10-K filed March 12, 2015.

[28] Ladenburg Thalmann Analyst Report dated November 6, 2015.

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while on pacritinib."[29] Through these Offering Materials, CTI successfully sold all of the stock that it offered, securing over $100 million in proceeds.

41. Unknown to investors who purchased CTI shares in the Offerings, the Company's representations about PERSIST-1 and pacritinib's "safety" were false, misleading and omitted material information. In truth, as the FDA would explain when it imposed its clinical hold after reviewing the study results, there was "excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial."[30] Indeed, in discussing the results for the PERSIST-1 clinical study, CTI and Defendant Bianco did not tell investors that almost twice the percentage of patients treated with pacritinib died within the first 24 weeks on the drug, as compared to those given the alternative treatment. CTI and Defendant Bianco also did not disclose to investors that was an imbalance in the percentage of severe cardiac events among the two study groups (grades 3 and 4 cardiac events), with patients receiving pacritinib also suffering nearly twice the percentage of severe cardiac events. Specifically, 11 of the 220 patients that took pacritinib died within the first 24 weeks, as compared to only 3 of the 107 patients who received the alternative treatment; and 21 of the patients who received pacritinib suffered severe cardiac events within the first 24 weeks, compared to only 6 patients who received alternative therapies. The undisclosed results are reflected in the below chart:

[29] Piper Jaffray Analyst Report dated November 2, 2015.

[30] CTI Press Release dated February 8, 2016.

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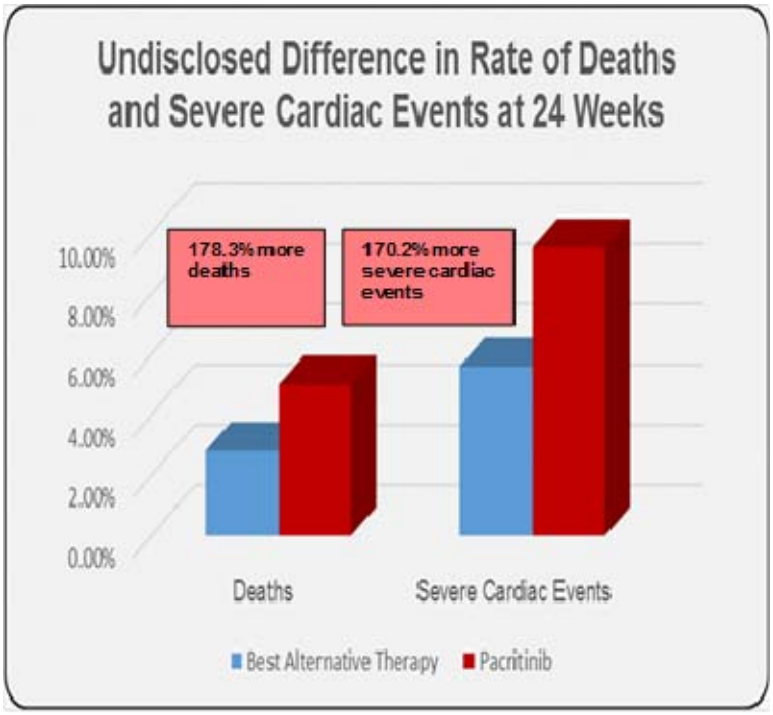

42. These results were not provided to investors; however, they were seen by the IDMC for the PERSIST-1 study, as discussed below. When the IDMC saw the data in February 2015, they expressed concerns to CTI and President Bianco about the drug's safety, including concerns about the "mortality," and recommended that CTI terminate the PERSIST-1 study and hold enrollment in PERSIST-2, which was CTI's second planned Phase 3 trial for pacritinib. CTI and its President Bianco instead pressed onward with the trials and the Offerings, disclosing only the supposed "positive" safety results of the PERSIST-1 study and never disclosing until after the Class Period the critical imbalance in deaths and cardiac events between the two groups of patients.

5. CTI Misleads Investors About The IDMC's Findings

43. CTI's study protocol for pacritinib, which was posted on the FDA's website, assured patients and investors that PERSIST-1 was overseen by an "independent data monitoring

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committee."[31] Data monitoring committees have been regularly used for Phase 3 trials for decades.[32] As the FDA has explained, it is important for the credibility of the studies for a drug company to use an independent data monitoring committee to oversee its Phase 3 clinical studies. When properly used, a data monitoring committee provides "additional, independent oversight that would enhance safety of study participants and the credibility of the product development."[33] Industry participants have similarly recognized that data monitoring committees are critical "to preserve the integrity and credibility of the trial."[34] This all assumes, of course, that the data monitoring committee is properly used. As Dr. Guarino has explained, "use of a data monitoring committee does not improve the credibility and objectivity of a study if the drug company rejects the data monitoring committee's safety findings and recommendations."

44. Data monitoring committees are "composed of clinicians with expertise in relevant clinical specialties and at least one biostatistician knowledgeable about statistical methods for clinical trials and sequential analysis of trial data."[35] Data monitoring committees are responsible for reviewing safety results as the trial progresses, assuring safety of the participants and assessing efficacy of the drug. "The most important responsibility of the [data monitoring committee] is the performance of ongoing reviews of the evolving safety and efficacy

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[31] Available at https://clinicaltrials.gov/ct2/show/record/NCT01773187?term=pacritinib+AND+CTI&rank=1.

[32] Susan S. Ellenberg, PhD, David L. DeMets, Thomas R. Fleming, *Data Monitoring Committees in Clinical Trials: A Practical Perspective*, p. 5 (John Wiley & Sons 2002).

[33] FDA – Regulatory Information, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm, at p. 23.

[34] Ellenberg, *supra*, at p. 14. Dr. Ellenberg explained, "The primary responsibilities of a data monitoring committee are to: (i) safeguard the interests of study patients; (ii) preserve the integrity and credibility of the trial in order that future patients may be treated optimally; and (iii) ensure that definitive and reliable results be available in a timely way to the medical community."

[35] FDA – Regulatory Information, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm, at p. 8.

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data by intervention group."[36] In conducting its safety reviews, the data monitoring committee is privy to interim comparisons and, thus, has "the clearest picture of the emerging balance of risks and benefits within the trial."

45. After reviewing the study results, the data monitoring committee makes recommendations to the drug company "sponsoring" the study. As the FDA has explained, "[a] fundamental responsibility of a [data monitoring committee] is to make recommendations to the sponsor … concerning the continuation of the study."[37] A data monitoring committee will make one of five recommendations: (i) continuation of the study; (ii) continuation of the study with minor modifications; (ii) continuation of the study with major modifications; (iii) temporary suspension of patient enrollment in the study; (iv) study intervention until some uncertainty is resolved; or (v) a complete stop of the study.

46. Data monitoring committees rarely recommend that a drug company terminate a clinical trial. As the FDA has explained, "[m]ost frequently, a DMC's recommendation after an interim review is for the study to continue as designed."[38] Professor of Biostatistics at the University of Pennsylvania, Susan S. Ellenberg, PhD, in her manuscript titled "*Data Monitoring Committees in Clinical Trials*," similarly observed that "a large majority of trials monitored by DMCs proceed, without early termination."[39] Dr. Guarino likewise explains that "it is rare,

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[36] Ellenberg, *supra*, at p. 29.

[37] FDA – Regulatory Information, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm, at p. 24.

[38] FDA – Regulatory Information, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm, at p. 24.

[39] Ellenberg, *supra*, at p. 34. Dr. Ellenberg focuses her research on practical problems and ethical issues in designing, conducting and analyzing data from clinical trials, including surrogate endpoints, data monitoring committees, clinical trial designs, adverse event monitoring, vaccine safety and special issues in cancer and AIDS trials. In addition to teaching, she serves as a senior statistician for several multicenter clinical trials and directs the Biostatistics Core of the Penn Center for AIDS Research. Prior to her current position, Dr. Ellenberg served as a Director in the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the FDA.

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indeed, for a data monitoring committee to identify safety concerns that warrant a recommendation that a drug company terminate a study."

47. In the event that a data monitoring committee takes the rare step of recommending that a drug company stop its Phase 3 trial due to safety concerns, the industry practice is to adhere to that recommendation. Dr. Guarino has explained that, "in my over 40 years in the pharmaceutical industry, I've never seen a company that has failed to follow a data monitoring committee's recommendation to stop a trial due to safety concerns. It's absolutely unheard of in our industry." In a published discussion piece in the journal *Statistics in Medicine*, Jay Herson, PhD, Professor in Biostatistics at Johns Hopkins University, stated that "[i]t would be difficult to believe that a sponsor would put itself in that situation" of overturning a data monitoring committee's recommendation to stop a trial, particularly because it would present "liability issues – for example, if there was any kind of serious toxicity or death."[40] And Duke University Professor of Biostatistics Dr. Stephen L. George reported in his *Survey of Monitoring Practices in Cancer Clinical Trials* that, when he surveyed the National Cancer Institute's 12 cooperative clinical groups responsible for hundreds of Phase 3 trials, he found that "[n]o group reported any trial in which the recommendation of the DMC to terminate or modify a trial was not adopted."[41]

48. Consistent with these accounts, companies have repeatedly adhered to a data monitoring committee's recommendations to terminate their studies. For example, in

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[40] Jay Herson, PhD, *Discussion*, Stat. in Med., Vol. 12, 493-495 (1993). Jay Herson works as a consultant or data monitoring committee member for several pharmaceutical, biotech and medical device firms. He also serves as a Senior Associate in Biostatistics, with a joint appointment in the Center for Clinical Trials, at Johns Hopkins Bloomberg School of Public Health, Baltimore. He previously formed a contract research organization that provided data management, biostatistical and regulator services on clinical trials for pharmaceutical, biotechnology and medical device firms.

[41] Stephen L. George, PhD, *A Survey of Monitoring Practices in Cancer Clinical Trials*, Stat. in Med., Vol. 12, 435-450 (1993). Stephen L. George is a Director of Biostatistics for the Duke Comprehensive Center. He has authored several books on clinical trials, translational science, and prognostic and predictive models.

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November 2015, the drug company Derma Sciences, Inc. followed the recommendation of its data monitoring committee to terminate the Phase 3 trial for its treatment of diabetic foot ulcers. In January 2016, Teva Pharmaceutical and Active Biotech followed the recommendation of their data monitoring committee to stop the Phase 3 trial of their multiple sclerosis treatment drug in light of data showing an imbalance in non-fatal cardiovascular side effects between the drug and control arm. In February 2016, Peregrine Pharmaceuticals followed the recommendation of its data monitoring committee to end its Phase 3 trials due to patient deaths in the drug arm of the trial. In June 2016, Galena Biopharma Inc. followed the recommendation of its data monitoring committee to terminate the Phase III trials of NeuVax. And, in July 2016, Tokai Pharmaceuticals Inc. followed the recommendation by its data monitoring committee to stop its Phase 3 ARMOR3-SV clinical trials.

49. Unknown to CTI investors until after the Class Period, the data monitoring committee for the pacritinib studies initially recommended in February 2015 that CTI "terminate the PERSIST-1 trial and hold enrollment of new patients in the PERSIST-2 trial."[42] The IDMC's recommendation was based on the "safety concerns, including mortality, in patients on pacritinib" – *i.e.*, the very reasons why the FDA would impose a clinical hold on the PERSIST studies nearly a year later. *Id.* The IDMC's initial recommendation was delivered to CTI in February 2015 and made final in June 2015, following the Company's review of the unblinded safety results showing the higher percentage of deaths in the pacritinib group. *Id.* Notwithstanding the IDMC's "safety concerns, including mortality, in patients on pacritinib," CTI did not follow the recommendation to stop the PERSIST-1 study.[43] Rather, the Company "decided to discharge" the members of the original IDMC due to supposed "concerns about the original IDMC's impartiality." *Id.*

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[42] CTI SEC Form 10-Q dated May 10, 2016.

[43] *Id.*

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50. Meanwhile, during the Class Period, investors were misled into believing that the PERSIST-1 studies were overseen by an independent data monitoring committee, and that the committee suggested just one, minor modification to the study protocol in June 2015. Indeed, CTI's description in the prospectus supplements and other SEC filings during the Class Period mentioned only that the IDMC had "recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival."[44] Significantly, its disclosures did not tell investors that:

- The IDMC had actually recommended in early 2015 that CTI "***terminate*** the PERSIST-1 trial and ***hold enrollment*** of new patients in the PERSIST-2 trial"[45];
- The IDMC's recommendation was based on safety concerns including the "***mortality,*** in patients on pacritinib," *id.*; and
- CTI "discharge[d]" the original members of the IDMC after the original IDMC made its findings. The purported reason for the firing was supposed "concerns about the original IDMC's impartiality." *Id.*

51. Here, in a sharp departure with industry norms, CTI did ***not*** follow the IDMC's recommendation, did ***not*** disclose the IDMC's recommendation to terminate the studies and, additionally, ***falsely reported*** that the IDMC had recommended just a minor tweak to the trial design when, in fact, the IDMC had recommended the complete termination of the studies due to "safety concerns, ***including mortality,*** in patients on pacritinib."[46] Indeed, CTI itself implicitly recognized that its Class Period disclosures were incomplete and misleading when it disclosed in a May 10, 2016 SEC filing – over a year after the fact – that the IDMC had "safety concerns, including mortality, in patients on pacritinib" that warranted immediately terminating the PERSIST studies in February 2015.

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[44] CTI Supplemental Prospectus dated October 27, 2015; CTI SEC Form 10-Q filed November 5, 2015.

[45] CTI SEC Form 10-Q filed May 10, 2016.

[46] *Id.*

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6. The FDA Imposes A Clinical Hold On Pacritinib And The SEC Commences An Investigation

52. In early 2016, the FDA reviewed the PERSIST-1 trial results. It found – just like the IDMC had a year earlier – "excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial."[47] Accordingly, on February 8, 2016, the Company disclosed that the FDA imposed a hold on the PERSIST-1 trial and instructed CTI that "clinical investigators may not enroll new patients or start pacritinib as initial or crossover treatment, and patients not deriving benefit after 30 weeks of pacritinib treatment should stop using pacritinib." *Id.*

53. One day later, on February 9, the FDA elevated its clinical hold of PERSIST-1 to a "full clinical hold" on all Phase 3 studies. The FDA's clinical hold order, which was issued pursuant to 21 C.F.R. § 312.42, required a complete stop of all clinical work. As CTI has acknowledged, "[u]nder the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately and no patients can be enrolled or start pacritinib as initial or crossover treatment."[48] The FDA's full clinical hold was again based on the imbalance in deaths among the study arms, which showed that pacritinib had "a detrimental effect on survival," with deaths from "intracranial hemorrhage, cardiac failure and cardiac arrest." *Id.* CTI announced that it had withdrawn its New Drug Application, and that the FDA had recommended that the Company request a meeting prior to submitting a response to the full clinical hold.

54. Investors were stunned by CTI's disclosures about pacritinib's true safety profile and the undisclosed results of the PERSIST clinical studies. When the news broke, the price of CTI shares plummeted by over ***73%*** in just two business days, erasing over ***$229 million*** in market value. Biotech columnist Adam Feuerstein summed up investor sentiment in a February 2016 article titled *Despite Many Drug Blowups, CTI Bio CEO Bianco Turns S--t Into Gold for*

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[47] CTI Press Release dated February 8, 2016.

[48] CTI Press Release dated February 9, 2016.

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Himself, in which he explained how the recent revelations were a "blowup" for CTI, with "the chance [that] CTI Bio resurrects pacritinib … slim to none." As Mr. Feuerstein explained, the FDA's clinical hold was the product of "alarming safety problems" evident in the previously-undisclosed PERSIST-1 trial results.

55. In the aftermath, CTI recently announced that the SEC has been investigating, and continues to investigate, the Company's disclosures concerning pacritinib and the IDMC. Through a Freedom of Information Act ("FOIA") request, Plaintiffs have learned that the SEC began its non-public investigation into CTI's disclosures in early August 2015. On October 23, 2015, the SEC sent a letter to the FDA's Center for Drug Evaluation and Research requesting "files and records maintained by the [FDA] that concerned CTI and, more specifically, those documents that relate to Pacritinib," as well as the opportunity to "informally interview or discuss with FDA employees" CTI and pacritinib. Next, in January 2016, the SEC issued a subpoena directly to CTI requesting internal and external communications related to the PERSIST trials, as well as "communications with the independent data monitoring committee, or IDMC." As CTI belatedly revealed in a May 10, 2016 SEC filing, the "SEC [has been] seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib."[49]

56. In its May 10, 2016 Form 10-Q for the quarter ending March 31, 2016, CTI admitted that over a year earlier, in February 2015, the IDMC found that CTI should "terminate the PERSIST-1 trial and hold enrollment of new patients in the PERSIST-2 trial." The IDMC's recommendation was based on the "safety concerns, including mortality, in patients on pacritinib" (*i.e.*, the very reasons why the FDA would impose a clinical hold on the PERSIST studies nearly a year later). The IDMC's recommendation was delivered to CTI in February 2015 and made final in June 2015, following the Company's review of the unblinded

[49] CTI SEC Form 10-Q filed May 10, 2016.

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safety results. As discussed above, notwithstanding the IDMC's concerns about the imbalance in patient deaths, CTI and Defendant Bianco took the unprecedented step of failing to follow the IDMC's recommendation to stop the PERSIST-1 study. Rather, they "decided to discharge" the members of the original IDMC due to purported "concerns about the original IDMC's impartiality."

57. With the SEC's investigation still ongoing, CTI's longtime founder and President for 25 years, Defendant Bianco, unexpectedly announced his immediate "resignation" from the Company. In response, *The Seattle Times* described how Bianco received compensation in 2015 of $7.1 million, which placed him the 13th highest paid CEO in the entire Pacific Northwest, notwithstanding that "the company [has] never earned an annual profit" and "faces an SEC inquiry concerning [its pacritinib] disclosures."[50]

58. To this day, CTI's pacritinib remains under the FDA's full clinical hold. CTI has not resubmitted its application following the FDA's hold order. Nor has CTI submitted final study reports or datasets for its two studies PERSIST-1 and PERSIST-2. In addition, CTI also has not conducted additional Phase 2 dose exploration studies for pacritinib in patients with myelofibrosis, despite the FDA's recommendation to do so.

59. Recently, in September 2016, CTI received notice that Shire plc terminated the licensing and commercialization agreement with CTI for pacritinib.[51] As the *Puget Sound Business Journal* explained in its October 25, 2016 report, the "collapse" of CTI and Baxter's agreement is the "latest setback for CTI." Indeed, "CTI BioPharma has gone through more than $2 billion of investors' money over its 24-year history" and has "nothing to show for it."[52]

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[50] Rami Grunbaum, *CEO Bianco Retires After 25 Years Running Profitless CTI BioPharma*, The Seattle Times, Oct. 3, 2016.

[51] Under CTI's 2013 agreement with Baxter, Baxalta Inc. was assigned Baxter's rights and obligations under the agreement. Baxalta was subsequently acquired by Shire plc.

[52] Casey Coombs, *CTI BioPharma Has 'Nothing Left Of Value In The Pipeline' After Deal Collapse, Analyst Says*, Puget Sound Business Journal, Oct. 25, 2016.

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60. The price of CTI's stock price has never recovered since the Class Period, and today is 77% below its average price during the Class Period.

C. Misleading Statements And Omissions In Violation Of The Securities Act

61. The October 2015 Offering and the December 2015 Offering were conducted pursuant to a "shelf" registration statement and prospectus dated November 21, 2014, filed with the SEC on Form S-3. The Registration Statement and Prospectus, together with the applicable prospectus supplements, as well as all SEC filings incorporated therein, are collectively referred to herein, as applicable to each Offering, as the "Offering Materials" or the "Registration Statement," unless otherwise indicated.

1. The October 2015 Offering

62. On October 27, 2015, CTI filed a Prospectus Supplement (the "October 2015 Prospectus Supplement") in connection with its $50 million offering of 50,000 shares of Series N-1 Preferred Stock, and 40 million shares of common stock issuable upon conversion thereof.[53] Through the October 2015 Offering, the Company sold all 50,000 preferred shares, which were converted to 40 million common stock shares, for net proceeds to the Company of approximately $46.7 million.

63. The October 2015 Prospectus Supplement purported to describe the safety results from the PERSIST-1 trial, including the number of adverse events experienced by participants given pacritinib. It stated, among other things, that only "[a] limited number of patients discontinued treatment due to side effects" and highlighted, for example, how "[t]here were no Grade 4 gastrointestinal events reported."

[53] No later than the 30th day after the original issuance date, "all outstanding shares of Series N-1 Preferred Stock . . . automatically convert[ed] into the number of shares of [CTI's] common stock determined by dividing the aggregate stated value of the Series N-1 Preferred Stock being converted by the conversion price then in effect." The initial per share conversion price was set as $1.25, subject to specified adjustments under certain circumstances.

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64. The Prospectus Supplement also purported to describe the IDMC's findings for pacritinib. On this subject, the Prospectus Supplement stated only that "[t]he Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." However, as discussed above, this description of the IDMC's conclusion and recommendation was false and misleading and omitted material information because (i) the IDMC had safety concerns of "*mortality*, in patients on pacritinib"; (ii) the results of the PERSIST-1 trial showed an unfavorable imbalance in the number of deaths between those patients given pacritinib and those provided alternative therapies; (iii) the imbalance of deaths in the pacritinib group led the IDMC to recommend that the Company *terminate* the PERSIST-1 trial and hold enrollment of PERSIST-2; and (iv) Defendants *rejected* the IDMC's termination recommendations.

65. The Prospectus Supplement also specifically incorporated by express reference the following SEC filings made by CTI: the 2014 annual report on Form 10-K filed on March 12, 2015, and amended on April 30, 2015 (the "2014 Form 10-K); and the quarterly reports on Form 10-Q filed on May 6, 2015, and August 6, 2015.

66. The 2014 Form 10-K, which was incorporated into the October 2015 Prospectus Supplement, discussed the purported "safety profile" of pacritinib, assuring investors that the safety results of PERSIST-1 were "consistent with prior Phase 2 trials" and that "the incidence of grade 3 events was lower than observed in Phase 2 trials." The 2014 Form 10-K also purported to describe the "adverse events" that occurred during PERSIST-1, stating among other things that "very few patients discontinued treatment while on pacritinib or required a dose reduction." CTI's quarterly report for Second Quarter 2015, filed on Form 10-Q on August 6, 2015, which was also incorporated by reference in the October 2015 Prospectus Supplement, contains similar

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statements regarding the purported results of the pacritinib studies and supposedly limited instances and types of side effects.

67. The August 6, 2015 Form 10-Q, like the Prospectus Supplement in which it was incorporated by reference, also touted pacritinib's purported safety profile and the results of the PERSIST-1 study, stating that only "[a] limited number of patients discontinued treatment due to side effects" and that "[t]here were no Grade 4 gastrointestinal events reported."

68. The statements identified above in paragraphs 62-67 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks. Once Defendants chose to make representations about pacritinib's "safety profile" and the PERSIST-1 trial results, they were bound to do so in a manner that would not mislead investors.

69. The statements identified above in paragraphs 62-67 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies but, instead, "decided to discharge" the IDMC due to supposed concerns about the "impartiality" of the original IDMC.

2. The December 2015 Offering

70. On December 4, 2015, CTI filed a Prospectus Supplement (the "December 2015 Prospectus Supplement") in connection with its $55 million offering of 55,000 shares of N-2 Preferred Stock, and approximately 50 million shares of common stock issuable upon conversion

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thereof.[54] Through the December 2015 Offering, the Company sold all 55,000 shares of preferred stock, which were converted to 50 million common stock shares, for net proceeds to the Company of approximately $52.8 million.

71. The December 2015 Prospectus Supplement repeated the statements from the October 2015 Offering Materials concerning the results from the PERSIST-1 trial. It also provided the purported safety results from the PERSIST-1 trial, stating that only "a limited number of patients discontinued treatment due to side effects" and highlighting, for example, that "[t]here were no Grade 4 gastrointestinal events reported."

72. The December 2015 Prospectus Supplement also incorporated by express reference the following SEC filings made by CTI, among others: the 2014 Form 10-K; the quarterly reports filed on Form 10-Q, which were filed on May 6, 2015, August 6, 2015, and November 5, 2015.

73. As discussed above at paragraph 66, the 2014 Form 10-K, which was incorporated into the December 2015 Prospectus Supplement, discussed the purported "safety profile" of pacritinib, assuring investors that the results of PERSIST-1 were "consistent with prior Phase 2 trials" and that "the incidence of grade 3 events was lower than observed in Phase 2 trials." The 2014 Form 10-K also purported to describe the "adverse events" that occurred during PERSIST-1, stating among other things that "very few patients discontinued treatment while on pacritinib or required a dose reduction." CTI's quarterly reports filed on Form 10-Q on August 6, 2015, and November 5, 2015, incorporated by reference in the December 2015 Prospectus Supplement, contained similar statements regarding the results of the pacritinib studies and the purportedly limited instances and types of side effects.

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[54] No later than the 30th day after the original issuance date, "all outstanding shares of Series N-2 Preferred Stock . . . automatically convert[ed] into the number of shares of [CTI's] common stock determined by dividing the aggregate stated value of the Series N-2 Preferred Stock being converted by the conversion price then in effect." The initial per share conversion price was set as $1.10, subject to specified adjustments under certain circumstances.

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74. The August 6, 2015 and November 5, 2015 Forms 10-Q, like the December 2015 Prospectus Supplement in which they were incorporated by reference, also touted the safety profile of pacritinib and the results of PERSIST-1, stating that only "[a] limited number of patients discontinued treatment due to side effects" and that "[t]here were no Grade 4 gastrointestinal events reported."

75. The November 5, 2015 Form 10-Q, which was incorporated by reference into the December 2015 Prospectus Supplement, purported to describe the IDMC's findings and recommendations, misleadingly stating only that "[t]he Independent Data Monitoring Committee, or IDMC, . . . for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." However, as discussed above, this description of the IDMC's conclusion and recommendation was false and misleading and omitted material information because (i) the IDMC had safety concerns of "*mortality,* in patients on pacritinib"; (ii) the results of the PERSIST-1 trial showed an unfavorable imbalance in the number of deaths between those patients given pacritinib and those provided alternative therapies; (iii) the imbalance of deaths in the pacritinib group led the IDMC to recommend that the Company *terminate* the PERSIST-1 trial and hold enrollment of PERSIST-2; and (iv) Defendants *rejected* the IDMC's recommendations due to supposed concerns about its "impartiality."

76. The statements identified above in paragraphs 70-75 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks. Once Defendants chose to make

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representations about pacritinib's "safety profile" and the PERSIST-1 trial results, they were bound to do so in a manner that would not mislead investors.

77. The statements identified above in paragraphs 70 through 75 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies but, instead, "decided to discharge" the IDMC due to supposed concerns about the "impartiality" of the original IDMC.

COUNT I
FOR VIOLATIONS OF SECTION 11 OF THE SECURITIES ACT
(AGAINST THE SECURITIES ACT DEFENDANTS)

78. Plaintiffs reallege the allegations contained in paragraphs 15-77 as if fully set forth herein, only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the Defendants to defraud Plaintiffs or members of the Class.

79. This Count is based on Defendants' statutory liability for false and materially misleading statements or omissions in the Registration Statement. This Count does not sound in fraud, and any allegations of knowing or deliberately reckless misrepresentations and/or omissions in the Registration Statement are excluded from this Count, except that any challenged statements of opinion or belief are alleged to have been materially misstated statements of opinion or belief.

80. This Count is asserted by Lead Plaintiff against CTI, Defendant Bianco (who signed the Registration Statement), the Executive Signatory and Director Defendants (who signed the Registration Statement), and the Underwriter Defendants for violations of Section 11

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of the Securities Act, 15 U.S.C. § 77k, on behalf of all persons who acquired CTI securities pursuant to the Registration Statement.

81. As alleged above, the Registration Statement and Offering Materials contained untrue statements and omissions of material fact concerning, among other things, the safety results observed in clinical trials of pacritinib and the IDMC's findings.

82. As the issuer of the registered securities, CTI is strictly liable for the untrue statements of material fact and material omissions described herein.

83. None of the other Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

84. Class members did not know, nor in the exercise of reasonable diligence could they have known, that the Registration Statement and Offering Materials contained untrue statements of material fact and omitted to state material facts required to be stated or necessary to make the statements identified above not misleading when they purchased or acquired the registered securities. As a direct and proximate result of the acts and omissions of the Defendants named in this Count in violation of the Securities Act, the Class suffered substantial damage in connection with its purchase of CTI securities sold through the Offerings.

85. This claim is brought within one year of discovery of the untrue statements and omissions in the Registration Statement and Offering Materials and within three years of its effective date.

86. By reason of the foregoing, the Defendants named in this Count are liable under Section 11 of the Securities Act to members of the Class who purchased or otherwise acquired the securities sold pursuant and/or traceable to the Registration Statement.

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COUNT II
FOR VIOLATIONS OF SECTION 12(a)(2) OF THE SECURITIES ACT
(AGAINST CTI AND THE UNDERWRITER DEFENDANTS)

87. Plaintiffs reallege the allegations contained in paragraphs 15-86 as if fully set forth herein, only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the Defendants to defraud Plaintiffs or members of the Class.

88. This Count is based on Defendants' statutory liability for false and materially misleading statements or omissions in the Registration Statement. This Count does not sound in fraud, and any allegations of knowing or deliberately reckless misrepresentations and/or omissions in the Registration Statement are excluded from this Count, except that any challenged statements of opinion or belief are alleged to have been materially misstated statements of opinion or belief.

89. This Count is asserted by Lead Plaintiff against CTI and the Underwriter Defendants for violations of Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of all persons who acquired CTI securities pursuant to the Registration Statement.

90. CTI and the Underwriter Defendants were sellers, offerors, and/or solicitors of purchasers of the shares offered pursuant to the Registration Statement.

91. As alleged above, the Registration Statement and Offering Materials contained untrue statements and omissions of material fact concerning, among other things, the safety results observed in clinical trials of pacritinib and the IDMC's findings.

92. By means of the Registration Statement, Defendants named in this Count, through one or more public offerings, solicited and sold CTI securities to members of the Class.

93. As the issuer of the registered securities, CTI is strictly liable for the untrue statements of material fact and material omissions described herein.

94. None of the Underwriter Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement

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were accurate and complete in all material respects. Had they exercised reasonable care, these Defendants would have known of the material misstatements and omissions alleged herein.

95. Class members purchased CTI securities pursuant to the materially untrue or misleading Registration Statement. Class members did not know, nor in the exercise of reasonable diligence could they have known, that the Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated or necessary to make the statements identified above not misleading when they purchased such securities.

96. This action is brought within one year of the date when Lead Plaintiff discovered or reasonably could have discovered the facts upon which this Count is based, and within three years of the date that the securities upon which this Count is brought were sold to the public.

97. By reason of the foregoing, CTI and the Underwriter Defendants are liable for violations of Section 12(a)(2) of the Securities Act to Class members who purchased securities sold pursuant to the Registration Statement. Such Class members also have the right to rescind and recover the consideration paid for such securities upon tender of their securities to CTI and the Underwriter Defendants, and to recover rescissory damages to the extent they have already sold such securities.

COUNT III
FOR VIOLATIONS OF SECTION 15 OF THE SECURITIES ACT
(AGAINST DEFENDANT BIANCO)

98. Plaintiffs reallege the allegations contained in paragraphs 15-97, only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the Defendants to defraud Plaintiffs or members of the Class. This Claim does not sound in fraud, and any allegations of knowing or deliberately reckless misrepresentations and/or omissions in the Registration Statement are specifically excluded from this Count, except that any challenged statement of opinion or belief made in connection with the Offerings is alleged to have been a materially misstated statement of opinion or belief when made at the time of the Offering.

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99. This Count is asserted by Lead Plaintiff against Defendant Bianco for violations of Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of all persons who acquired CTI securities pursuant to the Registration Statement.

100. As set forth in Counts One and Two above, CTI is strictly liable under Sections 11 and 12(a)(2) for untrue statements and omissions of material fact in the Registration Statement.

101. Defendant Bianco, by virtue of his positions, voting power, ownership, rights as against CTI, and/or specific acts was, at the time of the wrongs alleged herein and as set forth herein, a controlling person of CTI within the meaning of Section 15 of the Securities Act. Bianco also had the power and influence, and exercised the same, to cause CTI to engage in the acts described herein, including by causing CTI to conduct the Offerings pursuant to the Registration Statement.

102. By virtue of the conduct alleged herein, Defendant Bianco is liable for the aforesaid wrongful conduct and is liable, to the same extent that CTI is liable under Sections 11 and 12(a)(2) of the Securities Act, to members of the Class who purchased CTI securities pursuant and/or traceable to the Registration Statement.

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EXCHANGE ACT CLAIMS

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EXCHANGE ACT CLAIMS

In this separate section of the Complaint, Plaintiffs assert claims against CTI and Defendant Bianco for violations of the Securities Exchange Act of 1934, which imposes liability for additional misstatements and omissions made with scienter.

A. Exchange Act Parties

1. Exchange Act Plaintiffs

103. By Order filed September 2, 2016, the Court appointed DAFNA as Lead Plaintiff. As set forth in the accompanying certification, DAFNA purchased CTI securities during the Class Period and suffered damages as a result of the violations of federal securities laws alleged herein.

104. Additional Plaintiff Michael Li is an individual, who resides in Ontario, Canada. As set forth in the accompanying certification, Mr. Li purchased CTI securities during the Class Period and suffered damages as a result of the violations of federal securities laws alleged herein.

2. Exchange Act Defendants

a) Corporate Defendant

105. Defendant CTI BioPharma Corp. is a biopharmaceutical corporation located in Seattle, Washington. The Company's common stock trades under the ticker symbol "CTIC" on the NASDAQ stock exchange and on the Mercato Telematico Azionario ("MTA") in Italy. As of October 31, 2016, there were over 280 million shares of CTI common stock outstanding. Defendant CTI is named in Count IV (Section 10(b)) of the Exchange Act claims.

b) Defendant James A. Bianco

106. Defendant James A. Bianco was the principal founder, CEO and President of CTI. Defendant Bianco signed each of the Company's registration statements, and quarterly and annual reports incorporated therein, which as discussed below, contained false and misleading statements and omitted material facts. Defendant Bianco is named in Count IV (Section 10(b)) and Count V (Section 20(a)) of the Exchange Act claims.

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B. Additional Allegations For Exchange Act Claims

107. The factual allegations set forth in the Summary of Factual Allegations for the Securities Act Claims (paragraphs 25-60) are incorporated by reference and re-alleged as if fully stated herein.

1. CTI And Bianco Make Additional Misstatements And Omissions During Investor Conferences And Press Releases

108. Shortly before the start of the Class Period, the IDMC recommended to CTI and Bianco that CTI terminate the PERSIST studies due to patient deaths in the pacritinib group. As alleged above, the results of the PERSIST studies showed a critical imbalance in the safety results, with nearly twice the percentage of patients given pacritinib dying and suffering severe cardiac events within the first 24 weeks of the study. CTI and Defendant Bianco kept these facts hidden from investors throughout the Class Period.

109. On the first day of the Class Period, March 9, 2015, CTI issued a press release titled "CTI BioPharma And Baxter Announce Positive Top-Line Results From Phase 3 Persist-1 Trial Of Pacritinib For Patients With Myelofibrosis." In the press release, CTI highlighted how purportedly "[t]he safety profile in the PERSIST-1 trial was consistent with prior Phase 2 trials" and that "the incidence of grade 3 events was lower than observed in Phase 2 trials." The press release further stated that "[n]o grade 4 gastrointestinal adverse events were reported" and that "very few" – only "[t]hree patients" – purportedly "discontinued therapy" while on pacritinib.

110. On the same day, CTI also held an investor conference call to discuss the purported "top-line results from the PERSIST-1 Phase 3 trial of pacritinib." During the investor conference, Defendant Bianco said that "we were blown away by seeing the data," explaining that "the safety profile in PERSIST-1 was consistent with or actually better than what we saw in the published Phase II trials that we presented at [the American Society of Hematology ("ASH")] in 2013." In particular, he noted, "the incidence of all grades as well as grade 3 [adverse] events was lower than observed in the previous Phase 2 trials," that "no grade 4 [gastrointestinal]

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adverse events were reported," and that "[o]nly three patients discontinued therapy." Never once did Bianco mention that the trial results actually showed an imbalance in severe cardiac events and deaths between the study arms, which were so critical that even the Company's IDMC had recommended terminating the studies just weeks earlier based on them.

111. During the conference, analyst Bert Hazlett asked Jim Bianco if he could provide, among other things, "a little bit more detail with regard there [sic] a clarification of the safety profile of this. You said it appears consistent with Phase 2." In response, Bianco stated, "***Well, so we have data that it is. So we don't think it anymore. We know that it is.***" And, when asked if the 36-week and 48-week data for pacritinib showed similar results, Defendant Bianco further stated that "we have looked at the 36- and 48-week and we see exactly the same pattern."

112. Investors welcomed these assurances, and CTI's share price climbed. In a report following CTI's March 9 investor conference, analysts at Janney Capital Markets announced their "Buy" rating for the Company's stock, highlighting how "Pacritinib Has [an] Improved Safety Profile Versus Other JAK2s." The analysts further repeated management's representations that "[t]he side effect profile seen in the Phase III PERSIST-1 trial indicated that the drug was safe and tolerable, with a lower incidence of grade 3 events and no report of grade 4 gastrointestinal events." The analysts concluded by noting how, "[i]mportantly, the analysis [provided by management] indicates that very few patients [only 3] discontinued treatment…" In another analyst report issued that day, Piper Jaffray similarly highlighted how "[a]ccording to management, the safety profile in PERSIST-1 is consistent-with or better-than prior studies," reiterating Defendant Bianco's statement that there were "only 3 drop outs" and "no grade 4 AEs [*i.e.*, adverse events]."

113. Over the next weeks and months, CTI and Defendant Bianco made these same representations and presented these same results to investors in myriad contexts, with CTI and Defendant Bianco telling investors that they had the "data in hand" that supported their representations about pacritinib's safety profile and the PERSIST-1 trials. On May 6, 2015, for

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example, CTI published a press release that identified as a "Recent Clinical Highlight" that "the safety profile of pacritinib" during PERSIST-1 "was generally consistent with previous Phase 2 studies." Again, not a word was mentioned by Bianco or anyone else about how the PERSIST-1 trial results actually showed an imbalance in severe cardiac events and deaths between the study arms, which was so disconcerting that the Company's own IDMC recommended terminating the studies.

114. On May 30, 2015, CTI presented data from the PERSIST-1 trial at the 2015 American Society of Clinical Oncology ("ASCO Presentation"). The ASCO Presentation was authored by CTI's Director of pacritinib, James P. Dean, among others, funded by CTI, and read by Dr. Richard Mesa of the Mayo Clinic. Significantly, the ASCO Presentation included a PowerPoint slide that purported to show the percentage of patients in each study arm that had died. According to the slide, which was the fifth slide of the ASCO Presentation, an ***equal*** percentage of patients in the pacritinib and in the best-available-therapy groups of the study had died, *i.e.*, there was a ***perfect balance*** in the percentage of deaths between the two study arms. Specifically, the ASCO Presentation represented that just 1% of the patients in the comparative study arms had died, with only three deaths in the pacritinib study arm.

115. As investors would eventually learn, however, this slide included in the ASCO Presentation was highly misleading and omitted material information. The 2015 ASCO Presentation was supposed to be based on data through week 24 of the PERSIST-1 study; indeed, virtually every slide in the ASCO Presentation stated that it was based on an assessment "at week 24" of the study. However, CTI did ***not*** include data through 24 weeks in its one slide that showed the number of trial participants who had died. Rather, for this one slide, CTI used an artificial "data cut off" date of January 17, 2015. The reason for its doing so is now readily apparent: the 24-week data shows an imbalance in the number of deaths between the study groups, with nearly twice the percentage of patients in the pacritinib group having died by week 24 of the study. The undisclosed trial results shows this imbalance, as well as that ***11*** people had

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died in the pacritinib arm within the first 24 weeks of the study – *i.e.*, over 3 times more than the "3 deaths" reported in the ASCO Presentation. These true facts were kept from investors until after the Class Period.

116. Rather than reveal the true facts, CTI adopted, reiterated and acknowledged ownership of its data and findings presented during the ASCO Presentation. For example, on the same day, May 30, 2015, CTI issued a press release that bore the headline: "Phase 3 Pacritinib Study Shows Significant Clinically Meaningful Results In Patients With Myelofibrosis In Late-Breaking Session At ASCO 2015." CTI's press release stated that "CTI BioPharma Corp. [and Baxter] today announced data from PERSIST-1 . . . in a late-breaking oral session at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO), May 29-June 2, 2015 in Chicago, Ill." The press release highlighted how "the most common adverse events" were mild to moderate diarrhea, nausea, anemia, thrombocytopenia, and vomiting, and that of the 220 patients who received pacritinib in PERSIST-1, only "3 discontinued therapy," and only "13 patients required dose interruption (average one week) for diarrhea." CTI added that "[g]astrointestinal symptoms typically lasted for approximately one week and few patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported."

117. Over the next months, CTI and Defendant Bianco further confirmed to investors that they adopted the ASCO Presentation of CTI's data, stating that "***we*** presented . . . at ASCO"[55] and referring to "the first [PERSIST-1 study results] ***we recently completed and reported*** at ASCO by Dr. Mesa."[56] Accordingly, investors understood the ASCO presentation to have been made by CTI with CTI's data. For example, analysts at Janney Capital Markets

[55] CTI Biopharma Presentation at Piper Jaffray Healthcare Conference, Dec. 2, 2015.

[56] CTI Biopharma Sponsor Update San Diego 2015, Beth Mechling, the CTI Vice President of Medical Affairs, available at https://www.youtube.com/watch?v=i4BLC4RWBms.

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reported on June 1, 2015 that "[a]t ASCO, ***CTIC reported*** details from the Phase III PERSIST-1 pacritinib trial in myelofibrosis (MF)."

118. Investors responded favorably to the ASCO Presentation. For example, Piper Jaffray, in its June 1, 2015 analyst report called the "Pac Data an Unexpected Bright Spot in Rainy ASCO'15 Weekend," stated that "safety looking mostly as in previous studies." Similarly, Janney Capital Markets, in discussing CTI's ASCO Presentation, highlighted how the "Pacritinib Safety Profile makes it Appealing" and that "[t]he side effect profile seen in the Phase III PERSIST-1 trial indicated that the drug was safe and tolerable, with a lower incidence of grade 3 events[,] no report of grade 4 gastrointestinal events," and "[o]nly 3 patients discontinu[ing] therapy."

119. Over the remainder of the Class Period, Defendant Bianco and his CTI colleagues repeated and highlighted the purported results of the pivotal PERSIST-1 trial. In press releases (including those dated June 12 and August 6, 2015) and during investor conferences (including held on August 6 and September 29, 2015), Bianco continued to minimize the limited "adverse events" from the PERSIST-1 trials, stating that only "few patients discontinued treatment due to side effects" and again highlighting that only "3 discontinued therapy." He also emphasized how the "side effect profile [of pacritinib during the PERSIST-1 trials] was actually better than what we had seen in Phase 2." Again, no mention was made of the fact that, in actuality, there was an imbalance in deaths and serious cardiac events between the two groups.

120. Without true or complete information, financial analysts covering the Company continued to identify pacritinib's "safety" as a reason to purchase CTI's stock. For example, following CTI's investor conference on August 7, 2015, Janney Capital Markets issued a "BUY" analyst report describing how CTI "highlighted [during the conference the purported] positive data from the PERSIST-1 clinical study," which "demonstrat[ed] the safety and efficacy of pacritinib (PAC) treatment of myelofibrosis patients over best available therapy (BAT)." Likewise, following the ASCO Presentation, on June 1, 2015, Piper Jaffray reported that "CTI

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provided an update on PERSIST-1," and discussed the "manageable" gastrointestinal adverse effects, including only grade 3 diarrhea purportedly found in only 5% of the pacritinib patients.

121. Investors ultimately learned the true facts about pacritinib's "safety profile" and the PERSIST-1 studies. As discussed in paragraphs 52-53, in early February 2016, CTI announced that the FDA, after reviewing the data, found "excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial"– precisely as the IDMC had disclosed internally to CTI a year earlier.[57] As analysts explained at the time, the FDA's hold meant that "more patients in the pacritinib arm of the study were dying compared to patients in the control arm."[58]

122. CTI's shareholders have suffered greatly from CTI and Bianco's misrepresentations and omissions. The Company's two-day stock drop of over 73% following the revelations in early February 2016 was the greatest stock drop in CTI's 25-year history, erasing $230 million in market capitalization. Meanwhile, Bianco profited handsomely from his misstatements and omissions, as further discussed below at paragraph 133.

2. CTI And Bianco Made The False Statements And Omissions With Scienter

123. Numerous facts raise a strong inference that Bianco and CTI knew or were deliberately reckless in disregarding the true facts when making their false and misleading statements. These include the following:

124. *By the start of the Class Period, CTI and Bianco knew of the IDMC's findings and recommendation*. CTI and Bianco have now admitted, after the Class Period, that the IDMC for pacritinib recommended ***in February 2015*** that they should "terminate the PERSIST-1 trial and

[57] CTI Press Release dated February 8, 2016.

[58] Adam Feurerstein, *Despite Many Drug Blowups, CTI Bio CEO Bianco Turns S--t into Gold for Himself*, The Street, Feb. 15, 2016.

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hold enrollment of new patients in the PERSIST-2 trial."[59] They have further admitted that the IDMC's recommendation was based on "safety concerns, ***including mortality***, in patients on pacritinib"– *i.e.*, the precise reasons that the FDA provided when imposing a clinical hold order on the study a year later.[60] That Defendants Bianco and CTI misrepresented and concealed the imbalance in deaths and cardiac events for over a year ***after*** learning of the IDMC's conclusions and recommendation is powerful evidence of scienter. In addition, the fact that Defendants Bianco and CTI concealed from investors and misrepresented the fact that the IDMC recommended terminating the studies due to concerns about the mortalities provides further evidence of scienter.

125. *Bianco and CTI's response to the IDMC's findings and recommendations.* As discussed above at paragraph 47, it is highly unusual and, in fact, without known precedents, for a drug company to overturn a data monitoring committee's recommendation to terminate a study due to safety concerns about patients' deaths. Bianco and CTI's response following the IDMC's recommendation demonstrates their awareness of the IDMC's conclusion, as well as its significance. These actions included (i) meeting with the IDMC and reviewing the PERSIST-1 data with the IDMC; (ii) convening the PERSIST Steering Committee to review the IDMC's findings and recommendation; (iii) retaining a statistician and clinician to evaluate the drug's safety profile; and (iv) terminating the members of the IDMC based on purported "concerns about the original IDMC's impartiality."[61] That Defendant Bianco and his Company took these significant steps reflects their knowledge of the IDMC's recommendation and the deaths in the pacritinib group underlying it, which they nevertheless kept from investors for over a year.

126. *The results of PERSIST-1 were critical to the Company's financial well-being.* Pacritinib was by far the most prominent drug in CTI's pipeline, and PERSIST-1 was its most

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[59] CTI SEC Form 10-Q filed May 10, 2016.

[60] *Id.*, at p. 16.

[61] *Id.*

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important clinical trial. In speaking to investors, Defendant Bianco acknowledged the drug's significance to the Company's bottom line, "underscor[ing] the importance of [the] pacritinib program to the Company."[62] Defendant Bianco similarly recognized publicly that the PERSIST-1 study was "pivotal" and a "very big pivotal" study for the Company. Indeed, the significance of both are demonstrated by the fact that the Company's stock price plummeted by over 73% following news of the study's failure and safety concerns. Given the importance of PERSIST-1 and pacritinib to CTI, Bianco knew, or was deliberately reckless in not knowing, during the Class Period of the IDMC's recommendation in February 2015 to terminate the study and the unfavorable imbalance in deaths between the pacritinib and the alternative therapy groups.

127. *Defendant Bianco had intimate knowledge of the PERSIST study results.* Defendant Bianco, an MD and PhD, was the principal founder, long-time CEO, President and Board Member of CTI. He was one of only two management members on CTI's "Scientific Advisory Board," which "assist[s] the Board in its oversight of the Company's oncology portfolio and clinical trial design," as well as "assist[s] management with respect to … research and development activities in general [and] regulatory matters."[63] On the Company's website and elsewhere, Bianco was identified as the "chief architect of the company's portfolio strategy, leading the acquisition, development and commercialization."

128. Defendant Bianco stated that he was particularly focused on the PERSIST-1 trial results and personally reviewed them. For example, when asked at the March 9, 2015 investor conference whether he thought pacritinib's drug profile was consistent with the Phase II trials, he stated that "***Well, so we have data that it is. So we don't think it anymore. We know that it is.***" He further said that ***"we have looked at the 36- and 48-week [data from PERSIST-1] and we see exactly the same pattern."*** In a press release issued three days later, he was quoted as saying that the "'positive top-line pacritinib data [were] ***in hand***.'" Once again, in a December 2, 2015

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[62] Transcript of CTI Conference Call April 29, 2014.

[63] CTI SEC Form 10-K dated April 30, 2015.

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investor conference, when asked about his recent activities, Bianco told investors that he felt "***like I am a [FDA] medical reviewer"*** because he had been devoting his days to "seeing reports" and the "hyperlinks" of the PERSIST-1 study data. In light of his knowledge of the results and his deep personal involvement in the pacritinib trials, Defendant Bianco knew, or was deliberately reckless in not knowing, that the PERSIST-1 study showed a higher rate of deaths and severe cardiac events among those patients who received pacritinib.

129. *Bianco and CTI's "discharging" of the members of the IDMC.* As discussed above, Bianco and CTI terminated the members of the IDMC after it concluded that CTI should terminate the PERSIST trials. Bianco and CTI claimed in a May 10, 2016 filing that the Company's decision to discharge the IDMC a year earlier was based on "concerns about the original IDMC's impartiality." However, the original IDMC was "discharged" only ***after*** it had concluded that CTI should terminate the PERSIST studies. And, while CTI and Bianco now conveniently claim that they discharged the IDMC because of impartiality, they never before publicly mentioned any concerns about the IDMC's "impartiality."

130. *Defendant Bianco spoke repeatedly about the results of the PERSIST-1 study and pacritinib's safety profile.* On numerous occasions, Defendant Bianco publicly discussed the supposed "safety profile" of pacritinib, as well as the results of the study. He repeatedly referenced details about the PERSIST study results, for example, stating that the safety profile in PERSIST-1 was consistent with or actually better than what we saw in the published Phase II trials; that the incidence of grade 3 adverse events was lower than observed in Phase 2 trials; that no grade 4 gastrointestinal adverse events were reported; and that only three patients had discontinued therapy. He also signed all of the Company's SEC filings during the Class Period that described the IDMC's purported conclusions and recommendations. Having spoken and made representations about these matters so often, Defendant Bianco knew, or was deliberately reckless in not knowing, the imbalance in deaths and severe cardiac events evident in the PERSIST-1 study results.

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131. *Defendant Bianco knew that investor and analyst attentions were acutely focused on the results of the PERSIST-1 study and pacritinib's safety profile.* Bianco understood and publicly acknowledged that investors "think [pacritinib] is going to be the blockbuster for the company."[64] Indeed, based on the PERSIST-1 results provided to the market, financial analysts estimated that the market size for pacritinib exceeded $2 billion, with 50-75% of the Company's value derived from pacritinib. Bianco was thus well aware that the market was heavily relying on the accuracy of his statements.

132. *Federal regulations required CTI and Bianco to monitor the PERSIST-1 trials and report patient deaths.* To ensure the safety of research participants, federal regulations require sponsors of clinical trials to monitor the trial in real-time. As part of that obligation, sponsors are required to notify the FDA of any death within 7 days of their learning of the death.[65] According to the PERSIST study protocol, participants in the study were all expected to live for at least six months and, thus, any deaths were unexpected and needed to be reported. These reporting obligations make it hard to conceive that CTI and Bianco did not know of the imbalance in patient deaths and severe cardiac events observed in PERSIST-1.

133. *Defendant Bianco received substantial bonuses and compensation as a result of his misrepresentations and omissions.* Bianco was individually motivated to continue the PERSIST studies and to conceal any information that might interfere with the completion of the studies. For example, for 2014, Defendant Bianco received a special additional bonus of 30% due to completing enrollment in the PERSIST-1 Phase 3 clinical trial. Bianco's annual cash incentive bonus for 2015 was likewise directly tied to the continuation of the PERSIST trials, including a "Pacritinib 326 Enrollment Milestone," a "Pacritinib 325 Top Line Data" bonus, and a "Pacritinib Study Submitted" bonus. By misreporting the data, and concealing the IDMC's

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[64] Bianco's interview with Valerie Bauman, *A conversation with CTI's James Bianco, Part 1*, Puget Sound Business Journal, Aug. 31, 2012. http://www.bizjournals.com/seattle/news/2012/08/31/a-conversation-with-ctis-jim-bianco.html.

[65] 21 C.F.R. 312.32.

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findings and recommendations, Bianco ensured that the PERSIST trials continued, and the milestones were "achieved." As a result, he left the Company with $7.1 million in bonuses and compensation in 2015 alone, making him one of the highest-paid CEOs in the Pacific Northwest.

134. *CTI's use of an arbitrary cut-off date to present data from the PERSIST-1 trial that was more favorable than the 24-week data.* As discussed in paragraph 116, the 24-week data for the PERSIST-1 study showed an imbalance in deaths, with nearly twice the percentage of patients treated with pacritinib having died within the first 24 weeks of the study. CTI concealed this data from investors until after the Class Period. During the Class Period, CTI instead presented different, more favorable, data when talking about the number of pacritinib patients who died. Indeed, during the 2015 ASCO Presentation, the Company presented the 24-week data for virtually every metric and on every slide ***except*** the one slide that discussed the number of deaths among the comparative study groups. For this one slide, the Company used an arbitrary cut-off date and presented data from January 15, 2015 and earlier. By doing so, the Company conveyed a rosy picture, in which there was a perfect balance in patient deaths, with an equal 1% of patients in both study arms having died.

135. *Defendants Bianco and CTI delayed disclosure of the SEC's investigation.* Through a FOIA request, Plaintiffs' counsel recently learned that the SEC began an investigation into CTI's disclosures concerning pacritinib as early as August 2015. On October 23, 2015, the SEC sent a letter to the FDA's Center for Drug Evaluation and Research requesting "files and records maintained by the [FDA] that concerned CTI and, more specifically, those documents that relate to Pacritinib," as well as the opportunity to "informally interview or discuss with FDA employees" CTI and pacritinib. Then, in January 2016, the SEC issued a subpoena directly to CTI requesting internal and external communications related to the PERSIST trials, as well as "communications with the independent data monitoring committee, or IDMC." Meanwhile, CTI did not disclose the investigation until February 2016. That Defendants Bianco and CTI did not

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promptly disclose the SEC investigation, and instead continued to misrepresent pacritinib's safety profile, further supports an inference of scienter.

136. *Defendants Bianco and CTI were motivated by unique "milestone payments" and the terms of an "advance" that were contingent on positive results from the pacritinib trials.* CTI was eligible to receive from its partner, Baxter, up to $302 million in "milestone payments" that were expressly contingent on "the successful achievement of certain development and commercialization milestones" related to the pacritinib trials. For example, in its Form 10-K filed on March 12, 2015, CTI reported that it had received a $20 million payment "relating to the achievement of a clinical milestone" in connection with the first treatment dosing of the last patient enrolled in PERSIST-1. This milestone payment enabled CTI to report total revenues for the first three months of 2014 as $39.5 million compared to $0.4 million for the same period in 2013, and was largely responsible for CTI's total revenues for the first three quarters of 2014, including the $20 million development milestone payment and recognition of $0.6 million of the upfront payment under the Baxter Agreement. CTI was also given a $32 million milestone "advance" in June 2015 in light of its reaching certain milestones related to the development of pacritinib, with the terms of this "advance," obliging CTI to repay Baxter the $32 million advance, plus 9% interest, if the pacritinib studies were terminated. As a result of these milestone payments and the advance, which were critical to the Company's financials, CTI and Defendant Bianco were motivated to continue to misreport the study results and reject and conceal the IDMC's findings and recommendations.

137. *Defendant Bianco secured needed liquidity for his Company through stock offerings.* Shortly after the IDMC's recommendation to terminate the PERSIST studies, CTI completed three offerings for over $127 million. In the materials sent to investors in connection with these offerings, Defendants Bianco and CTI did not tell investors about the "safety concerns, including mortality, in patients on pacritinib." Nor did they tell investors that they took the rare step of rejecting the IDMC's safety recommendation. By failing to do so, and by

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providing inaccurate and incomplete data from the PERSIST-1 study, Defendants Bianco and CTI were able to complete the 2015 offerings.

138. *At the same time that Defendants Bianco and CTI were touting pacritinib, CTI executives were quietly exiting the Company.* Following the IDMC's recommendation to terminate the PERSIST-1 study, numerous CTI executives knowledgeable about the PERSIST studies exited the Company in rapid succession, including: Nels Royer, Senior Clinical Project Manager (left in April 2015); Amanda Kell, Director, Compliance (left in September 2015); Charity Aitken, Sr. Director of Analytical Development (left in October 2015); Patricia Taylor, Vice President Regulatory Affairs (left in October 2015); John Bauer, member of the Board of Directors (left in October 2015); Karen Ignagni, member of the Board of Directors (left in November 2015); Erica Harzewski, Manager, Clinical Data Management (left in December 2015); and Panteli Theocharous, Vice President Global Medical Affairs (left in December 2015). That executives knowledgeable about pacritinib and the trials left the Company at the same time that Bianco was touting pacritinib supports an inference of scienter.

139. *Defendant Bianco abruptly left CTI after the disclosure of the clinical hold, IDMC's findings, and the SEC investigation*. On October 3, 2016, following the FDA's clinical hold and the belated disclosure of the IDMC's recommendations, the Company announced that the prior day, October 2, 2016, Defendant Bianco, who had been with CTI for over 25 years, suddenly "resigned."[66] The immediate departure of the Company's long-time CEO occurred in the midst of an ongoing SEC investigation and after the truth about the increased mortality and other serious adverse events from pacritinib, as well as the IDMC's findings and recommendations, were revealed. Bianco's departure further strengthens the inference of scienter.

[66] CTI Press Release dated October 3, 2016.

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C. Misleading Statements And Omissions Violating The Exchange Act

1. Misleading Statements And Material Omissions Made In Early 2015

140. On March 9, 2015, the first day of the Class Period, CTI issued a press release titled "CTI BioPharma And Baxter Announce Positive Top-Line Results From Phase 3 Persist-1 Trial Of Pacritinib For Patients With Myelofibrosis." The press release emphasized pacritinib's purported safety, stating that "[t]he safety profile in the PERSIST-1 trial was consistent with prior Phase 2 trials" and that "the incidence of grade 3 events was lower than observed in Phase 2 trials." It further stated that "[n]o grade 4 gastrointestinal adverse events were reported" and that "very few" – only "[t]hree patients" – purportedly "discontinued therapy" while on pacritinib.

141. On the same day, CTI held an investor conference call to discuss the purported "top-line results from the PERSIST-1 Phase 3 trial of pacritinib." During the investor call, Defendant Bianco spoke about the purported safety of pacritinib as demonstrated by the PERSIST-1 data, again telling investors that "the safety profile in PERSIST-1 was consistent with or actually better than what we saw in the published Phase II trials that we presented at ASH in 2013." Defendant Bianco further claimed that "[o]nly three patients discontinued therapy."

142. During the conference, analyst Bert Hazlett asked Defendant Bianco, among other things: "[C]ould you maybe [give] a little bit more detail with regard there (sic) a clarification of the safety profile of this. You said it appears consistent with Phase 2." Bianco responded by stating, among other things: "Well, so we have data that it is. So we don't think it anymore. We know that it is." In addition, when asked if the 36-week and 48-week data showed a "better [] response rate," Defendant Bianco stated that "we have looked at the 36- and 48-week and we see exactly the same pattern."

143. On March 12, 2015, CTI conducted an earnings conference call to report the Company's financial results for the first quarter of 2015 (the "Fourth Quarter 2014 Earnings

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Conference Call"). During the call, Defendant Bianco assured investors that the Company had "share[d] the most important information in the [March 9, 2015] top-line release" relevant to pacritinib. That same day, CTI issued a press release in which it again highlighted the purportedly "positive top-line pacritinib data in hand."

144. Also on March 12, 2015, CTI filed the 2014 Form 10-K, which discussed the purported "safety profile" of pacritinib, assuring that the results of PERSIST-1 were "consistent with prior Phase 2 trials" and that "the incidence of grade 3 events was lower than observed in Phase 2 trials." The 2014 Form 10-K also purported to describe the "adverse events" that occurred during PERSIST-1, stating among other things that "very few patients discontinued treatment while on pacritinib or required a dose reduction."

145. The statements identified above in paragraphs 140-144 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks.

146. The statements identified above in paragraphs 140-144 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies.

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2. Misleading Statements And Material Omissions Made During The First Quarter Of 2015

147. On May 6, 2015, CTI issued a press release filed on Form 8-K, which announced CTI's financial results for the first quarter of 2015. In discussing the purported results of the PERSIST-1 Phase 3 clinical trial, the press release stated that "the safety profile of pacritinib was generally consistent with previous Phase 2 studies," in which there purportedly was "substantial and prolonged improvement in disease-related symptoms without causing clinically significant myelosuppression."

148. The statements identified above in paragraph 147 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks.

149. The statements identified above in paragraph 147 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies.

3. Misleading Statements And Material Omissions Made During The Second Quarter Of 2015

150. On May 30, 2015, CTI trial data from PERSIST-1 during the 2015 ASCO Presentation. The ASCO Presentation was authored by CTI's Director of pacritinib, James P. Dean, among others, funded by CTI, and read by Dr. Richard Mesa of the Mayo Clinic. The

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ASCO Presentation included a PowerPoint slide that purported to show the percentage of patients in each study arm that had died since the commencement of the trial. According to the slide, which was based on stale data up only through January 2015, there was an equal percentage of just 1% of patients in each study arm who had died.

151. On May 30, 2015, CTI issued a press release titled "Phase 3 Pacritinib Study Shows Significant Clinically Meaningful Results In Patients With Myelofibrosis In Late-Breaking Session At ASCO 2015." CTI's press release stated that "CTI BioPharma Corp. [and Baxter] today announced data from PERSIST-1 . . . in a late-breaking oral session at the 51st Annual Meeting of [ASCO]." The press release highlighted how "the most common adverse events" were mild to moderate diarrhea, nausea, anemia, thrombocytopenia, and vomiting, and that of the 220 patients who received pacritinib in PERSIST-1, only "3 discontinued therapy," and only "13 patients required dose interruption (average one week) for diarrhea." CTI added that "[g]astrointestinal symptoms typically lasted for approximately one week and few patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported."

152. On June 12, 2015, CTI issued a press release titled "Pacritinib Phase 3 Study Shows Positive Results In Patient Reported Outcomes Measuring Quality Of Life In Patients With Myelofibrosis." The press release purported to describe the safety results of the study "within 24 weeks," again representing that "[o]f the patients treated with pacritinib" only "3 discontinued therapy."

153. On August 6, 2015, CTI issued a press release, filed on Form 8-K, titled "CTI BioPharma Reports Second Quarter 2015 Financial Results." The press release again stated that only "[a] limited number of patients discontinued treatment due to side effects." Also on August 6, 2015, CTI filed a quarterly report on Form 10-Q, which discussed the purported safety profile of pacritinib, assuring that the results of PERSIST-1 revealed that "gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one

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week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented at a late-breaking oral session at the 51st Annual Meeting of [ASCO]."[67] CTI also held an investor conference on August 6, 2015, in which Bianco stated that "for all of the symptoms," "pacritinib showed a statistically significant improvement over best available therapy. You may recall the most common adverse event occurring with pacritinib within 24 weeks of any grade were mild to moderate GI symptoms – were the most common adverse event, and typically last for approximately a week. And only a handful of patients discontinued therapy due to a GI side effect. Importantly, there were no Grade 4 GI events. And the incidents of Grade 1 to 3 were lower than what we saw in our Phase II studies."[68]

154. The statements identified above in paragraphs 150-153 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks.

155. The statements identified above in paragraphs 150-153 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies but,

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[67] CTI SEC Form 10-Q filed August 6, 2015.

[68] August 6, 2015 Q2 2015 CTI Biopharma Earnings Call Transcript.

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instead, "decided to discharge" the IDMC due to supposed concerns about the "impartiality" of the original IDMC.

4. Misleading Statements And Material Omissions Made During The Third Quarter Of 2015

156. On September 23, 2015, CTI issued a press release titled "CTI BioPharma To Submit NDA For Pacritinib In Q4 Based Primarily On Data From Single Pivotal Persist-1 Trial." The press release purported to describe the findings of the IDMC, stating that "[t]he Independent Data Monitoring Committee (IDMC) for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." However, as discussed above, this description of the IDMC's conclusion and recommendation was false and misleading and omitted material information because (i) the IDMC had safety concerns of "*mortality,* in patients on pacritinib"; (ii) the results of the PERSIST-1 trial showed an unfavorable imbalance in the number of deaths between those patients given pacritinib and those provided alternative therapies; (iii) the imbalance of deaths in the pacritinib group led the IDMC to recommend that the Company *terminate* the PERSIST-1 trial and hold enrollment of PERSIST-2; and (iv) Defendants *rejected* the IDMC's recommendations due to supposed concerns about its "impartiality."

157. On September 29, 2015, CTI gave an investor presentation at the Ladenburg Thalmann Life Sciences Conference. During the presentation, Defendant Bianco highlighted pacritinib's purported safety profile, claiming that its "side effect profile [in PERSIST-1] was actually better than what we had seen in Phase 2."

158. On October 27, 2015, CTI filed a Prospectus Supplement (the "October 2015 Prospectus Supplement") in connection with its $50 million offering of 50,000 shares of Series N-1 Preferred Stock, and 40 million shares of common stock issuable upon conversion thereof. The October 2015 Prospectus Supplement purported to describe the safety results from the

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PERSIST-1 trial, including the number of adverse events experienced by participants given pacritinib. It stated, among other things that, only "[a] limited number of patients discontinued treatment due to side effects" and highlighted, for example, how "[t]here were no Grade 4 gastrointestinal events reported," and that "data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor)[,] pacritinib therapy resulted in a significantly higher proportion of patients with . . . control of disease-related symptoms."[69]

159. The Prospectus Supplement also purported to describe the IDMC's findings for pacritinib. On this subject, the Prospectus Supplement stated only that "[t]he Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." However, as discussed above, this description of the IDMC's conclusion and recommendation was false and misleading and omitted material information because (i) the IDMC had safety concerns of "*mortality*, in patients on pacritinib"; (ii) the results of the PERSIST-1 trial showed an unfavorable imbalance in the number of deaths between those patients given pacritinib and those provided alternative therapies; (iii) the imbalance of deaths in the pacritinib group led the IDMC to recommend that the Company *terminate* the PERSIST-1 trial and hold enrollment of PERSIST-2; and (iv) Defendants *rejected* the IDMC's recommendations due to supposed concerns about its "impartiality."

160. On November 5, 2015, CTI filed a quarterly report on Form 10-Q, which discussed the purported safety profile of pacritinib, again assuring that "[g]astrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented at a late-breaking oral session at the 51st Annual Meeting of [ASCO]."

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[69] CTI Prospectus Supplement dated October 27, 2015.

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161. The Form 10-Q added that "[a]dditionally, in June 2015, results from PERSIST-1 patient-reported outcome (PRO) and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation."

162. In addition, the Third Quarter Form 10-Q purported to describe the IDMC's findings and recommendations, stating only that "[t]he Independent Data Monitoring Committee, or IDMC, . . . for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." However, as discussed above, this description of the IDMC's conclusion and recommendation was false and misleading and omitted material information because (i) the IDMC had safety concerns of "*mortality*, in patients on pacritinib"; (ii) the results of the PERSIST-1 trial showed an unfavorable imbalance in the number of deaths between those patients given pacritinib and those provided alternative therapies; (iii) the imbalance of deaths in the pacritinib group led the IDMC to recommend that the Company *terminate* the PERSIST-1 trial and hold enrollment of PERSIST-2; and (iv) Defendants *rejected* the IDMC's recommendations due to supposed concerns about its "impartiality."

163. The statements identified above in paragraphs 156-162 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks.

164. The statements identified above in paragraphs 156-162 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events

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between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies but, instead, "decided to discharge" the IDMC due to supposed concerns about the "impartiality" of the original IDMC.

5. Misleading Statements And Material Omissions Made During The Fourth Quarter Of 2015

165. On December 4, 2015, CTI filed the December 2015 Prospectus Supplement in connection with its $55 million offering of 55,000 shares of N-2 Preferred Stock, and approximately 50 million shares of common stock issuable upon conversion thereof. The December 2015 Prospectus Supplement purported to describe the safety results from the PERSIST-1 trial, including the number of adverse events experienced by participants given pacritinib. It stated, among other things that, only "[a] limited number of patients discontinued treatment due to side effects" and highlighted, for example, how "[t]here were no Grade 4 gastrointestinal events reported," and that "data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor)[,] pacritinib therapy resulted in a significantly higher proportion of patients with . . . control of disease-related symptoms."[70]

166. On December 5, 2015, CTI also issued a press release titled "Analysis of Pivotal Phase 3 Patient Outcomes by Subgroups Shows Treatment with Pacritinib Resulted in Consistent Rates of Reduction in Spleen Volume and Symptom Burden." In it, Defendant Bianco highlighted how the PERSIST-1 data showed pacritinib's purported "differentiated efficacy and safety profile" compared to the best alternative therapy. The press release also purported to provide information about "adverse events in the pacritinib arm vs. BAT"; however, it did not

[70] CTI Prospectus Supplement dated December 4, 2015.

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mention that there was an imbalance in the rates of death and serious cardiac events between the two study arms, with nearly twice the percentage of patients treated with pacritinib having died within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events.

167. The statements identified above in paragraphs 165-166 about pacritinib's "safety profile" and the PERSIST-1 trial results were false and misleading because, in reality, the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms. Nearly twice the percentage of patients treated with pacritinib died within the first 24 weeks of the study, and almost the same imbalance existed in the percentages of patients suffering severe cardiac events in the first 24 weeks.

168. The statements identified above in paragraphs 165-166 also omitted material facts, including that (i) there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated with pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events; (ii) the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib; and (iii) CTI did not follow the IDMC's recommendation to stop the studies but, instead, "decided to discharge" the IDMC due to supposed concerns about the "impartiality" of the original IDMC.

D. The Truth Is Revealed

169. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class. Throughout the Class Period, CTI's stock price was artificially inflated as a result of Defendants' materially false and misleading statements and omissions, which were widely disseminated to the securities markets, securities analysts, and investors and created false impressions concerning, among other things, pacritinib's safety profile and clinical trial results.

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170. As a result of Defendants' materially false and misleading statements and omissions, Plaintiffs and other members of the Class purchased CTI securities at artificially inflated prices. Plaintiffs and other members of the Class were thus damaged when the truth concealed by Defendants' misstatements was revealed on February 8 and 9, 2016.

171. Two disclosures at the end of the Class Period revealed to the market the relevant truth and the false and misleading character of Defendants' statements and omissions.

172. On February 8, 2016, CTI disclosed to investors that the FDA had placed a partial clinical hold on CTI's clinical trials for pacritinib due to "excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial" – the same reasons for the IDMC's recommendations to terminate the study. Under the partial clinical hold, clinical investigators were prohibited from enrolling new patients or starting pacritinib as initial or crossover treatment. Patients who were taking pacritinib without benefit for 30 weeks of treatment were instructed to stop using the drug. In response to these disclosures, CTI's stock fell by over 60%, falling $0.68 per share to close at $0.44 on heavy trading volume.

173. On February 9, 2016, CTI revealed that the FDA had placed the Company's Investigational New Drug for pacritinib on a full clinical hold. The FDA stated that the survival results of PERSIST-1 were consistent with PERSIST-2, which "show[ed] a detrimental effect on survival" and with deaths "includ[ing] intracranial hemorrhage, cardiac failure and cardiac arrest." Following Defendants' February 9, 2016 disclosures, shares of CTI's stock fell over 40% during intraday trading on February 10, 2016, on unusually heavy volume of over 15 million shares.

174. The declines in CTI's stock price on February 8, 2016, and February 10, 2016, were a direct and proximate result of Defendants' fraudulent conduct being revealed to investors and to the market. It was entirely foreseeable that Defendants' materially false and misleading statements and omissions discussed herein would artificially inflate the price of CTI securities. It was also foreseeable that the price of CTI's securities would drop when the truth was revealed.

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E. Presumption Of Reliance For Exchange Act Claims

175. At all relevant times, the market for CTI common stock was efficient for the following reasons, among others:

(a) CTI's stock met the requirements for listing, and was listed and actively traded on the NASDAQ;

(b) As a regulated issuer, CTI filed periodic reports with the SEC;

(c) CTI regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire service and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) CTI was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public market place.

176. As a result of the foregoing, the market for CTI common stock reasonably promptly digested current information regarding CTI from all publicly available sources and reflected such information in the price of CTI's common stock and Preferred Shares. The preferred shares sold to investors in the October and December 2015 Offerings were automatically convertible to common stock, with the price of the preferred shares tied to the price of the common stock. All purchasers of CTI common stock and Preferred Shares during the Class Period suffered similar injury through their purchase of CTI common stock and Preferred Shares at artificially inflated prices, and a presumption of reliance applies.

177. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose.

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F. Inapplicability Of The Statutory Safe Harbor And Bespeaks Caution Doctrine

178. The statutory safe harbor of bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint. None of the statements complained of herein was a forward-looking statement. Rather, they were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including, for example, statements about the pacritinib study results and the IDMC's findings and recommendations, among others.

179. To the extent that any of the false and misleading statements alleged herein can be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As set forth in detail, then-existing facts contradicted Defendants' statements regarding the pacritinib study results and the IDMC's findings and recommendations, among others. Given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by CTI were not sufficient to insulate Defendants from liability for their materially false and misleading statements.

180. To the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those statements was made, the particular speaker knew that the particular forward-looking statement was false, and the false forward-looking statement was authorized and approved by an executive officer of CTI who knew that the statement was false when made.

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COUNT IV
VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER
(AGAINST CTI AND BIANCO)

181. This Count is asserted on behalf of all members of the Class against Defendants CTI and Bianco for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. These Defendants are liable for their course of conduct that operated as a fraud or deceit on purchasers of CTI securities by disseminating materially untrue and misleading statements and/or concealing material adverse facts, which caused Plaintiffs and other members of the Class to purchase CTI securities at artificially inflated prices.

182. Throughout the Class Period, CTI and the Defendant Bianco, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs and the Class; made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

183. These Defendants' materially false and misleading statements and omissions were made with scienter, made in connection with the purchase or sale of CTI securities, and were intended to and did, as alleged herein, (a) deceive the investing public, including Plaintiffs and the other members of the Class; (b) artificially create, inflate, and maintain the market for and market price of the Company's securities; and (c) cause Plaintiffs and other members of the Class to purchase CTI securities at artificially inflated prices.

184. CTI and the Defendant Bianco had a duty to promptly disseminate accurate and truthful information with respect to CTI's business and its products and to correct any previously issued statements that had become materially misleading or untrue.

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185. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for CTI securities, which inflation was removed from the respective securities when the true facts became known. Plaintiffs and the Class would not have purchased CTI securities at the prices they paid, or at all, if they had been aware that the market price of CTI common stock had been artificially and falsely inflated by these Defendants' false and misleading statements.

COUNT V
FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT
(AGAINST DEFENDANT BIANCO)

186. This Count is asserted on behalf of all members of the Class against Defendant Bianco for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

187. During his tenures as an officer and director of CTI, Defendant Bianco was a controlling person of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of his position of control and authority as an officer and director of CTI, Defendant Bianco had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. Defendant Bianco was able to and did control, directly and indirectly, the content of the public statements made by CTI during the Class Period, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

188. As more fully described above, in his capacity as a senior corporate officer of the Company, Defendant Bianco had direct involvement in the day-to-day operations of the Company, in reviewing and managing the Company's regulatory and legal compliance, and in its public reporting of pacritinib clinical trial data, including drafting, reviewing, and approving statements concerning those data. Defendant Bianco made numerous false and misleading statements on CTI's behalf at investor conferences, in press releases, on earnings calls, and in reports with the SEC.

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189. As set forth above, CTI violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person of CTI and as a result of his own aforementioned conduct, Defendant Bianco is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiffs and the other members of the Class who purchased or otherwise acquired CTI securities.

190. As a direct and proximate result of these Defendants' conduct, Plaintiffs and the other members of the Class suffered damages in connection with their transactions in CTI securities.

III. CLASS ACTION ALLEGATIONS

191. Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a Class consisting of all persons and entities who purchased or otherwise acquired CTI securities (i) pursuant or traceable to CTI's October and December 2015 Securities Offerings, and were damaged thereby; and (ii) between March 9, 2015, through February 9, 2016, inclusive and were damaged thereby. Excluded from the Class are Defendants, the officers and directors of CTI during the Class Period (the "Excluded Officers and Directors"); members of the immediate families of Individual Defendants and of the Excluded Officers and Directors; any entity in which any Defendant, any Excluded Officer or Director, or any of their respective immediate family members had during the Class Period and/or has a controlling interest; Defendants' liability insurance carriers; any affiliates, parents, or subsidiaries of CTI; all CTI plans that are covered by ERISA; and the legal representatives, heirs, agents, affiliates, successors-in-interest or assigns of any excluded person or entity, in their respective capacity as such.

192. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, CTI shares were actively traded on the NASDAQ.

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As of October 31, 2016, CTI had approximately 280 million shares of common stock issued and outstanding. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds-of-thousands of members of the proposed Class. Class members who purchased CTI securities may be identified from records maintained by CTI or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

193. Plaintiffs' claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal laws as complained of herein.

194. Plaintiffs will fairly and adequately protect Class members' interests and have retained competent counsel experienced in class actions and securities litigation.

195. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether the Defendants made statements to the investing public during the Class Period that were false, misleading or omitted material facts; and

(c) the proper way to measure damages.

196. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation make it impossible for such members to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

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IV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Awarding such equitable/injunctive or other further relief (including, but not limited to, rescission) as the Court may deem just and proper.

V. JURY DEMAND

197. Plaintiffs hereby demand a trial by jury.

Dated: November 8, 2016

Respectfully submitted,

By: */s/ Roger M. Townsend*

Roger M. Townsend, WSBA #25525
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Counsel for Lead Plaintiff DAFNA and Additional Plaintiff Michael Li and Lead Counsel for the Class

CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2016, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system, which will send notification of such filing to the email addresses of participants in the case who are registered CM/ECF users. Non-CM/ECF registrants will be duly and properly served with Summons and Complaint in accordance with the Federal Rules of Civil Procedure.

/s/ Roger M. Townsend
ROGER M. TOWNSEND

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CERTIFICATION PURSUANT TO
THE FEDERAL SECURITIES LAWS

I, Howard Nurtman, on behalf of the Court-appointed Lead Plaintiff DAFNA LifeScience, LP and DAFNA LifeScience Select, LP (the "DAFNA Funds"), hereby certify, as to the claims asserted under the federal securities laws, that:

1. I am the Director of Compliance and Risk Management at DAFNA Capital Management, LLC. I am authorized to sign this certification on behalf of the DAFNA Funds. I have reviewed the Consolidated Class Action Complaint in this matter and authorize its filing by counsel.

2. The DAFNA Funds did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any action arising under the federal securities laws.

3. The DAFNA Funds fully understand the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the Class.

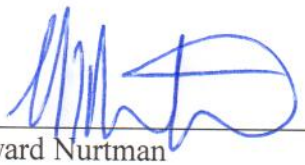
4. The DAFNA Funds' transactions in the CTI BioPharma Corp. securities that are the subject of this action are set forth in the chart attached hereto.

5. The DAFNA Funds have sought to serve and were appointed as lead plaintiffs on behalf of a class in the following action under the federal securities laws filed during the three-year period preceding the date of this Certification:

   In re CTI BioPharma Corp. Sec. Litig., No. 16-cv-216 (W.D. Wash.)

6. The DAFNA Funds will not accept any payment for serving as a representative party on behalf of the Class beyond the DAFNA Funds' pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 4th day of November, 2016.



Howard Nurtman
Director of Compliance and Risk Management
DAFNA Capital Management, LLC

The DAFNA Funds
Transactions in CTI BioPharma Corp.

DAFNA LifeScience, LP

Transaction	Date	Shares	Price
Sale	3/9/2015	(789,000)	2.8752
Purchase	4/2/2015	115,027	1.8928
Purchase	4/6/2015	178,900	1.8869
Purchase	4/7/2015	119,500	1.9083
Purchase	4/9/2015	6,400	1.8900
Sale	5/28/2015	(26,200)	1.9348
Sale	5/29/2015	(393,627)	1.8999
Purchase[1]	10/27/2015	960,000	1.2500
Sale	10/27/2015	(1,000)	1.5000
Purchase[2]	12/4/2015	1,110,000	1.1000
Sale	12/18/2015	(800)	1.2500
Sale	12/21/2015	(60,000)	1.2527
Sale	12/24/2015	(17,000)	1.3000
Sale	12/28/2015	(60,000)	1.3163
Sale	1/5/2016	(30,000)	1.3100

[1] The fund bought shares of Series N-1 Preferred Stock, offered at a price to the public of $1,000 per share of Series N-1 Preferred Stock, convertible at any time into 800 shares of common stock at a conversion price of $1.25 per share of common stock. This security was converted on 10/27/2015 into shares of common stock.

[2] The fund bought shares of Series N-2 Preferred Stock, offered at a price to the public of $1,000 per share of Series N-2 Preferred Stock, convertible at any time, subject to certain limitations, into shares of common stock at a conversion price of $1.10 per share of common stock. This security was converted on 12/4/2015 into shares of common stock.

The DAFNA Funds
Transactions in CTI BioPharma Corp.

DAFNA LifeScience Select, LP

Transaction	Date	Shares	Price
Sale	3/9/2015	(505,300)	2.8752
Purchase	4/2/2015	80,565	1.8928
Purchase	4/6/2015	124,508	1.8869
Purchase	4/7/2015	83,400	1.9083
Purchase	4/9/2015	4,500	1.8900
Sale	5/28/2015	(17,615)	1.9348
Sale	5/29/2015	(275,358)	1.8999
Purchase[1]	10/27/2015	640,000	1.2500
Sale	10/27/2015	(1,000)	1.5000
Purchase[2]	12/4/2015	708,181	1.1000
Sale	12/18/2015	(500)	1.2500
Sale	12/21/2015	(40,000)	1.2527
Sale	12/24/2015	(7,500)	1.3000
Sale	12/28/2015	(35,000)	1.3163
Sale	1/5/2016	(17,854)	1.3100
Sale	2/8/2016	(400)	0.8000

[1] The fund bought shares of Series N-1 Preferred Stock, offered at a price to the public of $1,000 per share of Series N-1 Preferred Stock, convertible at any time into 800 shares of common stock at a conversion price of $1.25 per share of common stock. This security was converted on 10/27/2015 into shares of common stock.

[2] The fund bought shares of Series N-2 Preferred Stock, offered at a price to the public of $1,000 per share of Series N-2 Preferred Stock, convertible at any time, subject to certain limitations, into shares of common stock at a conversion price of $1.10 per share of common stock. This security was converted on 12/4/2015 into shares of common stock.

CERTIFICATION PURSUANT TO THE FEDERAL SECURITIES LAWS

I, Michael Li, hereby certify, as to the claims asserted under the federal securities laws, that:

1. I have reviewed the Consolidated Securities Class Action Complaint in this matter and authorize its filing by counsel.

2. I did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any action arising under the federal securities laws.

3. I am willing to serve as a representative party on behalf of the Class, including providing testimony at deposition and trial, if necessary.

4. My transactions in the CTI BioPharma Corp. securities that are the subject of this action are set forth in the chart attached hereto.

5. I have not sought to serve as a lead plaintiff or representative party on behalf of a class in any action under the federal securities laws filed during the three-year period preceding the date of this Certification.

6. I will not accept any payment for serving as a representative party on behalf of the Class beyond my pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2 day of November, 2016.

Michael Li

Michael Li
Transactions in CTI BioPharma Corp.

Transaction	Date	Shares	Price
Purchase	7/8/2015	1,000	1.8999
Purchase	7/8/2015	9,900	1.9097