**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| [redacted] Individually and On Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>ARIAD PHARMACEUTICALS, INC., HARVEY J. BERGER, FRANK G. HALUSKA, TIMOTHY P. CLACKSON, and EDWARD M. FITZGERALD,<br><br>Defendants. | **Case No.** 13-cv-12544<br><br>**CLASS ACTION**<br><br>**COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS**<br><br>**DEMAND FOR JURY TRIAL** |

## CLASS ACTION COMPLAINT

Plaintiff [redacted] individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Ariad Pharmaceuticals, Inc. ("ARIAD" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased ARIAD securities between December 12, 2011 and October 8, 2013, inclusive (the "Class Period"), seeking to recover damages caused by defendants' violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. ARIAD is a global oncology company focused on the discovery, development and commercialization of medicines to transform the lives of cancer patients. The Company's approach to structure-based drug design has led to several molecularly targeted medicines for drug-resistant or difficult-to-treat cancers.

3. Throughout the Class Period, Defendants represented that the Company's leukemia drug Iclusig (ponatinib), based on its clinical data from its pivotal PACE trial of Iclusig, was safe and effective, without serious adverse events such as serious arterial thrombotic and cardiovascular events. Specifically, on December 11, 2011, ARIAD announced preliminary clinical data from the PACE trial, which purportedly yielded "strong clinical evidence of the anti-leukemic activity of ponatinib". Moreover, the Company touted the "favorable safety and tolerability profile of ponatinib". Based upon these representations, the Company achieved FDA approval for Iclusig on December 14, 2012.

4. On October 9, 2013, the Company updated the data from its PACE trial, revealing that the drug was shown to cause a higher rate of blood clots and heart-related side effects than previously disclosed. Specifically, the Company disclosed that serious arterial thrombosis occurred in a staggering 11.8% of Iclusig-treated patients, and that 6.2% of the patients had cardiovascular events and 4.0% had cerebrovascular events. As a result, the FDA placed a hold

on new patient enrollment for Iclusig testing, and the Company advised patients currently receiving the drug to lower their dosage.

5. On this news, ARIAD shares declined $11.31 per share or nearly 66%, to close at $5.83 per share on October 9, 2013.

6. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant damages.

## JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections l0(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule l0b-5 promulgated thereunder by the SEC, 17 C.F.R § 240.10b-5.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). ARIAD maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

10. In connection with the acts alleged in this complaint, 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 the national securities markets.

## PARTIES

11. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased ARIAD securities at artificially inflated prices during the Class Period and was damaged thereby.

12. Defendant ARIAD is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business at 326 Landsdowne Street, Cambridge, MA 02139. ARIAD's common stock trades on the NASDAQ Global Market ("NASDAQ") under the ticker symbol "ARIA."

13. Defendant Harvey J. Berger ("Berger") was, at all relevant times, the Company's Chairman, President and Chief Executive Officer.

14. Defendant Frank G. Haluska ("Haluska") was, at all relevant times, the Company's Senior Vice President and Chief Medical Officer.

15. Defendant Timothy P. Clackson ("Clackson") was, at all relevant times, the Company's President of Research and Development, Senior Vice President and Chief Scientific Officer.

16. Defendant Edward M. Fitzgerald ("Fitzgerald") was, at all relevant times, the Company's Executive Vice President, Chief Financial Officer and Treasurer.

17. The defendants referenced above in ¶¶ 13-16 are referred to herein as the "Individual Defendants."

## SUBSTANTIVE ALLEGATIONS

## BACKGROUND

18. ARIAD is a global oncology company with a mission to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need – aggressive cancers where current therapies are inadequate. The Company focuses on commercializing its first approved cancer medicine, Iclusig (ponatinib), and developing additional molecularly targeted therapies to treat patients with blood cancers and solid tumors.

19. On December 14, 2012, the Company obtained accelerated approval from the U.S. Food and Drug Administration ("FDA") to sell its first new cancer medicine, Iclusig. Iclusig is a TKI approved in the United States for the treatment of adult patients with chronic, accelerated or blast phase CML, who are resistant or intolerant to prior TKI therapy, and the treatment of adult patients with Ph+ALL, who are resistant or intolerant to prior TKL therapy.

## MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

20. On December 11, 2011, after the market closed, the Company issued a press release announcing preliminary data from its Pivotal PACE Trial of ponatinib. Specifically, the Company stated the following, in relevant part:

> ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) today announced preliminary clinical data from the pivotal PACE trial -- a fully enrolled and ongoing Phase 2 study of its investigational pan-BCR-ABL inhibitor, ponatinib, in patients with chronic myeloid leukemia (CML) or Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL), who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation. These initial data demonstrate that 47 percent of chronic-phase CML patients in the trial achieved a major cytogenetic response to date, including 65 percent of patients who have a T315I mutation. Approximately half of these patients had no more than a single bone-marrow assessment, while the remainder had two or more assessments.
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> "The preliminary findings from the global PACE trial confirm strong clinical evidence of the anti-leukemic activity of ponatinib in patients who are resistant or intolerant to dasatinib or nilotinib, or who have the T315I mutation for which there are no currently available treatments," stated Jorge Cortes, M.D., professor and deputy chair, Department of Leukemia, The University of Texas M.D. Anderson Cancer Center, Houston, TX.
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> "These results are very attractive even at this early stage of the study when most patients have only had one or two assessments for cytogenetic response because of the short follow-up," he added. "We know from the Phase 1 clinical trial of ponatinib that response rates increase over time, and we expect this to be the same on PACE. We are very pleased with the strength of these preliminary data that are similar to initial response results reported in the Phase 1 setting."
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**Safety profile (N=449)**

Initial safety data show ponatinib to be well tolerated.

The most common adverse events considered related to ponatinib included rash (in 32% of patients), thrombocytopenia (31%), dry skin (24%), abdominal pain (19%), and headache (17%). Elevated serum lipase, nausea, fatigue and myalgia were observed less frequently. These effects were mostly grade 1 or 2 and were well tolerated by patients in the trial.

The incidence of pancreatitis across the study and including all grades was 6%. No patient discontinued participation in the trial due to pancreatitis. Pancreatitis was previously determined to be the dose-limiting toxicity of ponatinib in the Phase 1 trial.

Four on-study deaths were deemed by investigators as possibly or probably related to ponatinib treatment; three of these had advanced-phase CML or Ph+ ALL. All four of these patients had complex, confounding medical conditions. Based on data entered into the clinical database by investigators, the deaths were due to pneumonia, fungal pneumonia, gastric hemorrhage and cardiac arrest (one each). There was no evidence of any ponatinib-specific findings emerging.

"These preliminary results of the PACE trial show beneficial responses to ponatinib and a molecular response rate that already compares favorably to MMR rates seen with imatinib -- the most commonly used treatment for newly diagnosed CML patients," said Frank G. Haluska, M.D., Ph.D., vice president and chief medical officer of ARIAD. "The early response rates are highly encouraging, with a 47 percent major cytogenetic response rate in this heavily pretreated patient population with chronic-phase CML, including a 65 percent major cytogenetic response rate in patients with the T315I mutation for whom none of the approved therapies is effective."

"Importantly, this initial assessment of the PACE trial provides further evidence of a favorable safety and tolerability profile of ponatinib in resistant or intolerant CML patients. The adverse event profile is similar to what was seen in the earlier Phase 1 study of ponatinib, although the incidence of pancreatitis is less in the PACE trial. The four deaths that were deemed to be treatment related were likely linked to the advanced nature of their disease, including the myelosuppressive effects of ponatinib on already badly damaged bone marrows," added Dr. Haluska.

21. On February 28, 2012, the Company announced financial results for its fourth quarter and year ended December 31, 2011 and provided an update on corporate developments. The press release stated the following relevant part:

> **Advancing Ponatinib to Potential U.S. Commercialization by 1Q of 2013**
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> We expect our investigators to present updated clinical data from the PACE trial at the annual meeting of the American Society of Clinical Oncology in June, 2012. These data will form the basis of our regulatory filings for marketing approval of ponatinib in the U.S., Europe and other geographies.
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> We had a successful Pre-NDA meeting with the U.S. Food and Drug Administration (FDA). Regulatory filings in the U.S. and in Europe are proceeding as planned for submission in 3Q of 2012.
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> We secured agreement with U.S. and European regulatory authorities on the design of a Phase 3 trial of ponatinib in patients with newly diagnosed CML and the regulatory paths going forward. We expect the global trial to begin in 3Q of 2012 and to have the following features:
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> - Approximately 500 patients randomized 1:1
> - Ponatinib *vs.* imatinib, each given at standard doses
> - Primary endpoint of major molecular response rate at 12 months
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> We showed that ponatinib can be administered with or without a meal (*i.e.,* no food effect) and has no effect on cardiac repolarization (*i.e.,* no QT prolongation) in patients – both important differentiators, especially in the newly diagnosed CML setting.
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> We plan to file the investigational clinical trial application for ponatinib in Japan in 1H of 2012 and begin a Phase 1/2 clinical trial in 2H of 2012.
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> We have been providing ponatinib to patients with CML and Ph+ALL through an investigator-sponsored IND program in the U.S. and a named-patient program in Europe. We expect to begin an expanded access program in the U.S. in 1Q of 2012 and a broader international program in 2Q of 2012.

22. On February 29, 2012, the Company filed an annual report with the SEC on a Form 10-K for the year ended December 31, 2011 which was signed by, among others Defendants Berger and Fitzgerald. In addition, the Form 10-K contained certifications pursuant

to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

23. The 10-K represented the following in relevant part concerning the Company's pivotal PACE trial and ponatinib:

> Ponatinib is an investigational pan BCR-ABL inhibitor that we believe has broad potential applications in various hematological cancers and solid tumors. Ponatinib was internally discovered and is wholly owned by us. Results from preclinical studies showed that ponatinib potently inhibits BCR-ABL, a target protein associated with drug-resistant CML, as well as various mutants of BCR-ABL.
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> Preclinical studies also showed that ponatinib demonstrated efficacy and oral dosing flexibility in animal models of CML, including forms of CML caused by clinically relevant mutants of BCR-ABL. Significantly, ponatinib potently inhibited a specific mutant, T315I, which is resistant to all currently marketed drugs. Additional preclinical studies demonstrated that ponatinib also inhibits Flt3, a target associated with acute myeloid leukemia, or AML.
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> In addition, in preclinical studies ponatinib has demonstrated potent inhibition of additional targets implicated in the initiation and progression of multiple cancers, including the receptors for vascular endothelial growth factors, or VEGFRs, fibroblast growth factors, or FGFRs, and angiopoietin, or Tie2. Based on ponatinib's differentiated profile, we believe these findings support the broad potential of this product candidate not only in CML and Ph+ ALL, but also in other hematological cancers, such as AML, and various solid tumors.
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> In December 2011, we announced preliminary clinical data from the pivotal PACE trial at the American Society of Hematology, or ASH, conference. The initial data demonstrated that 47 percent of chronic phase CML patients in the trial achieved a major cytogenetic response to date, including 65 percent of patients who had the T315I mutation. Approximately half of these patients had no more than a single bone-marrow assessment, while the remainder had two or more assessments. Initial safety data showed ponatinib to be well tolerated. We expect to conduct a complete analysis of the maturing PACE clinical trial data in preparation for our planned submission of a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, and a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in the third quarter of 2012.

24. On April 2, 2012, the Company issued a press release announcing new clinical data on ponatinib. Specifically, the press release stated the following in relevant part:

> The first study, "Ponatinib, a potent pan-BCR-ABL inhibitor, retains activity against gatekeeper mutants of FLT3, RET, KIT, PDGFR and FGFR1," was presented yesterday and shows that ponatinib overcomes resistant gatekeeper mutations well beyond BCR-ABL -- the drug's target in chronic myeloid leukemia (CML) and Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL) -- in other clinically relevant tyrosine kinase targets.
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> The preclinical research conducted by ARIAD scientists assessed the activity of ponatinib using cell lines expressing activated forms of FLT3, RET, KIT, PDGFR and FGFR1, each a kinase target associated with a specific tumor type. Ponatinib potently inhibited the activity of these kinases and maintained potent activity against gatekeeper variants that have been shown to cause resistance to other tyrosine kinase inhibitors in acute myeloid leukemia, medullary thyroid cancer, gastrointestinal stromal tumor (GIST) and rare forms of leukemia driven by these tyrosine kinases.
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> "Ponatinib was designed to block the abnormal tyrosine kinase, BCR-ABL, which drives CML and Ph+ALL," said Timothy P. Clackson, Ph.D., president of research and development and chief scientific officer of ARIAD. "The structural design feature that allows ponatinib to evade the BCR-ABL T315I gatekeeper mutation also enables the molecule to overcome analogous mutations in its other kinase targets. We are actively working with academic collaborators to set up clinical trials aimed at determining the potential role of ponatinib in these additional forms of drug-resistant cancer."

25. On May 9, 2012, the Company announced financial results for its first quarter ended March 31, 2012 and provided development progress. The press release stated the following relevant part:

> Updated clinical data from the pivotal PACE trial of ponatinib, our investigational pan-BCR-ABL inhibitor in patients with chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ALL), will be presented at the annual meeting of the American Society of Clinical Oncology (ASCO) on Monday, June 4, 2012. The ASCO presentation will include at least six months of available response data from all patients enrolled in the trial and will form the basis of our regulatory filings for marketing approval of ponatinib in the U.S., Europe and other geographies.

26. On May 9, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended March 31, 2012 which was signed by Defendants Berger and Fitzgerald. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

27. The 10-Q represented the following in relevant part:

> Ponatinib, previously known as AP24534, is an investigational pan BCR-ABL inhibitor that we believe has potential applications in various hematological cancers and solid tumors. In the third quarter of 2011, we completed patient enrollment in a pivotal Phase 2 clinical trial of ponatinib in patients with resistant or intolerant chronic myeloid leukemia, or CML, or Philadelphia positive acute lymphoblastic leukemia, or Ph+ ALL. Subject to further patient follow-up and data analysis in this trial, we expect to file for marketing approval of ponatinib in the United States and Europe in the third quarter of 2012 with potential regulatory approval in the United States as soon as the first quarter of 2013. Subject to obtaining marketing approval, we intend to commercialize ponatinib in the United States and Europe and other select markets worldwide. We also plan to initiate additional clinical trials of ponatinib, including a Phase 3 clinical trial in newly diagnosed CML patients, and commence clinical trials of ponatinib in Japan, in the second half of 2012.

28. On June 4, 2012, the Company issued a press release announcing updated data from pivotal PACE Trial of ponatinib. The press release stated the following in relevant part:

> ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) today announced updated clinical data from the pivotal PACE trial of its investigational pan-BCR-ABL inhibitor, ponatinib, in patients with chronic myeloid leukemia (CML) or Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL), who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation. These data show that 54 percent of chronic-phase CML patients in the trial, including 70 percent of patients who have a T315I mutation, achieved a major cytogenetic response. ARIAD expects to file for regulatory approval of ponatinib in the U.S. and the EU in the third quarter of 2012 based on these clinical data.
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> "The findings from the global PACE trial of ponatinib confirm its impressive anti-leukemic activity in patients with CML at all stages who are resistant or

intolerant to dasatinib or nilotinib, or who have the T315I mutation for which there are no currently available treatments," stated Jorge Cortes, M.D., professor and deputy chair, Department of Leukemia, The University of Texas M.D. Anderson Cancer Center, Houston, TX.

"Clinical responses to ponatinib were observed in patients regardless of their mutation status or disease stage," he added. "Of particular importance, responses to ponatinib appear to be durable, with 93 percent of chronic-phase CML patients projected to remain in major cytogenetic response at one year, clearly highlighting the potency of ponatinib."

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- ***Safety profile (N=449)***

    - Updated safety data show ponatinib to have a favorable profile in these heavily pretreated patients.
    - The most common adverse events considered related to ponatinib included thrombocytopenia (in 35% of patients), rash (32%), dry skin (30%), abdominal pain (22%), and headache (18%). Elevated serum lipase, fatigue and arthralgia were observed less frequently.
    - The incidence of pancreatitis across the study and including all grades was 6%. Pancreatitis was previously determined to be the dose-limiting toxicity of ponatinib in the Phase 1 trial.

"These updated findings of the PACE trial show beneficial responses and an increasing molecular response rate to ponatinib," said Frank G. Haluska, M.D., Ph.D., senior vice president and chief medical officer of ARIAD. "Importantly, these data provide clear evidence of a favorable safety and tolerability profile of ponatinib in resistant or intolerant CML patients. The adverse event profile is similar to what was seen in the earlier Phase 1 study of ponatinib, although the incidence of pancreatitis is less in the PACE trial," added Dr. Haluska.

29. On June 18, 2012, the Company issued a press release announcing updated data from pivotal PACE Trial of Ponatinib. The press release stated the following in relevant part:

ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) today announced updated clinical data from the pivotal PACE trial of its investigational pan-BCR-ABL inhibitor, ponatinib, in patients with chronic myeloid leukaemia (CML) or Philadelphia-positive acute lymphoblastic leukaemia (Ph+ ALL), who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation. These data show that 54 percent of chronic-phase CML patients in the trial, including 70 percent of patients who have a T315I mutation, achieved a major cytogenetic response.

The PACE trial data were featured on Sunday at 8:30 a.m. (CET) in an oral presentation at the 2012 European Hematology Association (EHA) annual congress taking place in Amsterdam, The Netherlands. ARIAD expects to file for regulatory approval of ponatinib in the EU and in the U.S. in the third quarter of 2012 based on these clinical data.

"The pivotal PACE trial data show robust anti-leukaemic activity of ponatinib in patients with CML at all stages, who are resistant or intolerant to dasatinib or nilotinib, or who have the T315I mutation, a rare form of CML which has no available treatment options," said Jane F. Apperley, professor and chair, Department of Haematology at the Imperial College, and the chief of service, Clinical Haematology, at the Imperial College Healthcare NHS Trust, London, England. "Clinical responses to ponatinib were observed in patients regardless of their mutation status or disease stage, and the responses appear to be durable, with 93 percent of chronic-phase CML patients projected to remain in major cytogenetic response at one year. This clearly highlights the potency of ponatinib."

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- ***Safety profile (N=449)***

    - Updated safety data show ponatinib to have a favorable profile in these heavily pretreated patients.
    - The most common adverse events considered related to ponatinib included thrombocytopenia (in 35% of patients), rash (32%), dry skin (30%), abdominal pain (22%), and headache (18%). Elevated serum lipase, fatigue and arthralgia were observed less frequently.
    - The incidence of pancreatitis across the study and including all grades was 6%. Pancreatitis was previously determined to be the dose-limiting toxicity of ponatinib in the Phase 1 trial.
      "These updated findings of the PACE trial show beneficial responses and an increasing molecular response rate to ponatinib," said Frank G. Haluska, M.D., Ph.D., senior vice president and chief medical officer of ARIAD. "Importantly, these data provide clear evidence of a favourable safety and tolerability profile of ponatinib in resistant or intolerant CML patients. The adverse event profile is similar to what was seen in the earlier Phase 1 study of ponatinib, although the incidence of pancreatitis is less in the PACE trial," added Dr. Haluska.

30. On July 27, 2012, the Company issued a press release announcing the initiation of the randomized Phase 3 trial of ponatinib in adult patients with newly diagnosed chronic myeloid leukemia (CML). The press release stated the following in relevant part:

> The **EPIC** (**E**valuation of **P**onatinib versus **I**matinib in **C**hronic Myeloid Leukemia) trial is designed to provide definitive clinical data to support regulatory approval of ponatinib in treatment-naïve CML patients. The efficacy of ponatinib will be assessed in comparison to imatinib based on evaluation of the primary endpoint of major molecular response (MMR) rate at 12 months. ARIAD expects to complete patient enrollment in the trial by the end of 2013.
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> "The start of the EPIC trial represents an important milestone in the development of ponatinib in CML and builds on the strong clinical data that we have obtained to date in patients with more advanced disease. We have designed the EPIC trial with comprehensive and well-aligned input from key opinion leaders and regulatory authorities in the United States, Europe and Japan and anticipate strong interest from investigators and their patients," stated Harvey J. Berger, M.D., chairman and chief executive officer of ARIAD.
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> Dr. Berger added, "The treatment of newly diagnosed CML patients has shifted in recent years to the use of second-generation BCR-ABL inhibitors. The EPIC trial will evaluate whether ponatinib – a pan-BCR-ABL inhibitor – produces anti-leukemic responses in these newly diagnosed patients and potentially prevents the emergence of resistance mutations seen with other tyrosine kinase inhibitors."

31. On July 30, 2012, the Company issued a press release announcing the submission of a New Drug Application ("NDA") for its investigational BCR-ABL inhibitor, Ponatinib to the FDA. The press release stated the following in relevant part:

> ARIAD's NDA is a rolling submission that includes all sections of the application and will be completed by the addition of a final subset of routine chemistry, manufacturing, and controls (CMC) data that the Company plans to submit to the FDA later in the third quarter. The FDA has communicated to ARIAD that it intends to begin immediate, comprehensive review of the NDA based on today's rolling submission. ARIA anticipates approval and commercial launch of ponatinib in the U.S. in the first quarter of 2013.
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> Results from the ongoing Phase 2 PACE trial of ponatinib reported in June at this year's annual meeting of the American Society of Clinical Oncology showed that 54 percent of chronic-phase CML patients who were resistant or intolerant to tyrosine kinase inhibitor therapy in the trial, including 70 percent of patients who have a T315I mutation, achieved a major cytogenetic response (MCyR) – the primary endpoint of the PACE trial. Thirty percent of these same patients achieved a major molecular response (MMR). MMR is the primary endpoint of ARIAD's Phase 3 EPIC trial comparing ponatinib to imatinib that is now underway in newly diagnosed chronic-phase CML patients.

32. On August 2, 2012, the Company announced financial results for its second quarter ended June 30, 2012 and provided development progress relating to ponatinib. The press release stated the following relevant part:

***Ponatinib Moving Closer to Potential U.S. Commercialization in 1Q of 2013***

- A New Drug Application (NDA) is now under review by the U.S. Food and Drug Administration (FDA) for U.S. marketing approval of ponatinib in patients with resistant or intolerant chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). ARIAD's NDA is a rolling submission that includes all sections of the application and will be completed by the addition of a small subset of routine chemistry, manufacturing, and controls (CMC) data that will be submitted later in the third quarter. The FDA has communicated to ARIAD that it intends to begin immediate, comprehensive review of the NDA based on this rolling submission. ARIAD is seeking accelerated approval of ponatinib and has requested a priority review of the application. The Company anticipates approval and commercial launch of ponatinib in the U.S. in the first quarter of 2013.

- Regulatory submission preparations for ponatinib in the European Union are advancing on schedule for submission this quarter. The Committee for Medicinal Products for Human Use (CHMP) recently granted an accelerated assessment designation for the ponatinib marketing authorization application (MAA) potentially decreasing the regulatory review time. An accelerated assessment is granted to product candidates that address major unmet medical needs or constitute a significant improvement over currently available therapies.

- A Phase 3, global clinical trial of ponatinib in patients with newly diagnosed CML is now underway and enrolling patients. The EPIC (**E**valuation of **P**onatinib versus **I**matinib in **C**hronic Myeloid Leukemia) trial is a randomized, two-arm, multicenter trial that compares the efficacy of ponatinib with that of imatinib in adult patients with newly diagnosed CML in the chronic phase.
- Among several important design features, the EPIC trial provides for an interim analysis of efficacy, which will take place 12 months after half of the patients in the trial have been randomized. The interim analysis will focus on the primary endpoint of the major molecular response rate at 12 months of treatment and, depending on the results, may allow ARIAD to file for regulatory approval of ponatinib in the newly diagnosed CML clinical setting approximately six months earlier than otherwise. ARIAD anticipates full patient enrollment in the study by the end of 2013.

- A Phase 1/2 clinical trial of ponatinib in Japan is expected to begin on schedule in the third quarter. The trial is designed to establish a recommended dose of ponatinib in Japanese patients, confirm its anti-leukemic activity in this patient

population, and provide the necessary data required for initial regulatory approval of ponatinib in Japan.

- More than 250 patients with CML and Ph+ALL in 16 countries are now receiving ponatinib through expanded access programs, including an expanded access protocol in the U.S. and a named-patient program in Europe.

33. On August 9, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended June 30, 2012 which was signed by Defendants Berger and Fitzgerald. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

34. The 10-Q represented the following in relevant part concerning ponatinib:

> Ponatinib is an investigational pan BCR-ABL inhibitor that we believe has potential applications in various hematological cancers and solid tumors. In the third quarter of 2011, we completed patient enrollment in a pivotal Phase 2 clinical trial of ponatinib, which we refer to as the PACE trial, in approximately 450 patients with resistant or intolerant chronic myeloid leukemia, or CML, or Philadelphia positive acute lymphoblastic leukemia, or Ph+ ALL, who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation. In June 2012, we announced updated clinical data from the PACE trial that showed that 54% of chronic-phase CML patients in the trial, including 70% of patients who have a T315I mutation, achieved a major cytogenetic response. The most common adverse events considered related to ponatinib included thrombocytopenia, rash, dry skin, abdominal pain, and headache.
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> We have filed for regulatory approval of ponatinib in the United States based on the results of the PACE clinical trial and expect potential regulatory approval as soon as the first quarter of 2013. We also expect to file for regulatory approval of ponatinib in Europe in the third quarter of 2012. Subject to obtaining marketing approval, we intend to commercialize ponatinib in the United States and Europe and other select markets worldwide. We have initiated a Phase 3 clinical trial of ponatinib in newly diagnosed CML patients. We plan to initiate additional clinical trials of ponatinib, including a clinical trial of ponatinib in Japan, in the second half of 2012.

35. On September 27, 2012, the Company issued a press release announcing the completion of its rolling submission of the NDA for ponatinib to the FDA. The press release stated the following in relevant part:

> ARIAD provided the FDA with remaining chemistry, manufacturing, and controls (CMC) data. ARIAD is seeking U.S. marketing approval of ponatinib in patients with resistant or intolerant chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). The Company has requested accelerated approval and a priority review of the ponatinib application by the FDA.
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> "In late July, we submitted the NDA for ponatinib ahead of schedule and, at the request of the FDA, in advance of having the final CMC data. We look forward to continuing our progress towards making ponatinib available to patients with CML and Ph+ ALL," stated Harvey J. Berger, M.D., chairman and chief executive officer of ARIAD. "If approved, we believe that ponatinib will become an important new medicine for CML and Ph+ ALL patients who have become resistant or intolerant to prior tyrosine kinase inhibitor therapy."

36. On November 7, 2012, the Company announced financial results for its third quarter ended September 30, 2012 and provided development progress. The press release stated the following relevant part:

> **Ponatinib Clinical Development Progress**
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> - The U.S. Food and Drug Administration (FDA) accepted for filing the New Drug Application (NDA) of ponatinib in patients with resistant or intolerant CML or Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). The FDA granted ARIAD's request for Priority Review of ponatinib and established an action date of March 27, 2013 under the Prescription Drug User Fee Act (PDUFA). The Company anticipates approval and commercial launch of ponatinib in the U.S. in the first quarter of 2013.
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> - ARIAD also submitted a Marketing Authorization Application (MAA) for ponatinib to the European Medicines Agency (EMA). ARIAD is seeking marketing approval in the European Union of ponatinib in adult patients with resistant or intolerant CML or Ph+ ALL. The Committee for Medicinal Products for Human Use (CHMP) granted ARIAD's request for accelerated assessment of the MAA, potentially decreasing the regulatory review time. ARIAD anticipates approval of ponatinib in the E.U. in the third quarter of 2013.

- Approximately 100 patients with CML or Ph+ALL at 23 centers in the U.S. are now receiving ponatinib through an expanded access protocol. Forty of these patients are in the chronic-phase of the disease. Patients on this expanded access protocol could be eligible to transition to commercial use of ponatinib following its anticipated approval early next year. These U.S. patients are part of a broad, global expanded access program that includes more than 400 patients, some of whom are receiving ponatinib through compassionate-use programs.

- ARIAD will present follow-up data from the pivotal Phase 2 PACE trial at the upcoming American Society of Hematology (ASH) Annual Meeting that will be held in Atlanta, GA, December 8 to 11, 2012. The ASH presentation will include 12 months of available response rate and duration of response data from the patients enrolled in the trial.

- Patient enrollment is underway in the global, Phase 3 EPIC trial of ponatinib in patients with newly diagnosed CML. This trial compares ponatinib to imatinib and has a primary endpoint of major molecular response at 12 months. ARIAD anticipates full patient enrollment in the trial by end of 2013, and the study includes an interim analysis of the primary endpoint 12 months after half of the approximately 500 patients in the trial have been enrolled.

37. On November 9, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the third quarter ended September 30, 2012 which was signed by Defendants Berger and Fitzgerald. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

38. The 10-Q represented the following in relevant part concerning ponatinib:

> Ponatinib is an investigational pan BCR-ABL inhibitor that we believe has potential applications in various hematological cancers and solid tumors. In the third quarter of 2011, we completed patient enrollment in a pivotal Phase 2 clinical trial of ponatinib, which we refer to as the PACE trial, in approximately 450 patients with resistant or intolerant chronic myeloid leukemia, or CML, or Philadelphia positive acute lymphoblastic leukemia, or Ph+ ALL, who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation. In June 2012, we announced updated clinical data from the PACE trial that showed that 54% of chronic-phase CML patients in the trial, including 70% of patients

> who have a T315I mutation, achieved a major cytogenetic response. The most common adverse events considered related to ponatinib included thrombocytopenia, rash, dry skin, abdominal pain, and headache.

39. On November 28, 2012, the Company issued a press release announcing publication of ponatinib Phase I Clinical Trial Results in the New England Journal of Medicine. The press release stated the following in relevant part:

> The Phase 1 dose-escalation study of ponatinib enrolled 81 patients with resistant hematologic cancers, including 60 patients with CML and five patients with Ph+ ALL. With median follow-up at 73 weeks, 72 percent of patients (31 of 43) with chronic-phase CML enrolled in the study had a major cytogenetic response (MCyR), including 92 percent (11 of 12) who had the T315I gatekeeper mutation, which is the most common mutation among resistant patients. It was estimated that 89 percent of patients with chronic-phase CML who had a MCyR would remain in response at 1 year (95% confidence interval, 69% to 96% by Kaplan–Meier analysis). Of 22 patients with accelerated-phase or blast-phase CML or Ph+ ALL, 36 percent (8 of 22) had a major hematologic response, and 32% (7 of 22) had a MCyR.
>
> Dose-limiting toxicities reported in the study included elevated lipase or amylase levels and pancreatitis. The most common treatment-related adverse events included rash (32%), thrombocytopenia (27%), arthralgia (17%), increased lipase (15%), fatigue (14%), acneiform dermatitis (14%), dry skin (14%), and nausea (14%). Neutropenia, headache, hypertriglyceridemia and myalgia occurred less frequently. The incidence of pancreatitis was 14% across all dose levels in the trial. The onset of pancreatitis, elevated amylase, and elevated lipase was dose-related with regard to both incidence and timing.
>
> "These findings demonstrate that ponatinib is a highly active agent in patients with CML who had become resistant to one or more tyrosine kinase inhibitors," stated Jorge Cortes, M.D., professor and deputy chair, department of leukemia, The University of Texas M.D. Anderson Cancer Center. "The response rates observed in this study confirm substantial and durable clinical activity and suggest that ponatinib may overcome BCR-ABL mutation-based resistance, as well as resistance when no mutations are detectable."

40. On December 9, 2012, the Company issued a press release announcing 12-month data from Pivotal PACE Trial of ponatinib in heavily pretreated chronic-phase CML patients. The press release stated the following in relevant part:

The study now shows that 56 percent of chronic-phase CML patients in the trial, including 70 percent of patients with a T315I mutation, achieved a major cytogenetic response (MCyR), the primary end-point for chronic-phase CML patients.

* * *

"The 12-month results from the global PACE trial of ponatinib reinforce its impressive anti-leukemic activity in heavily pretreated CML patients, regardless of their mutation status or disease stage," stated Jorge Cortes, M.D., professor and deputy chair, Department of Leukemia, The University of Texas M.D. Anderson Cancer Center, Houston, TX.

"Ponatinib demonstrated early responses in chronic-phase patients with thirty-four percent of these patients achieving a major molecular response and fifteen percent of those patients achieving a complete molecular response," he added. "Of particular importance, responses to ponatinib appear to be durable, with 91 percent of chronic-phase CML patients projected to remain in major cytogenetic response at one year."

***

- ***Safety profile (N=449)***

    - The most common non-hematologic treatment-emergent adverse events in the PACE trial included rash (in 38% of patients), abdominal pain (38%), headache (35%), dry skin (35%), and constipation (34%), with the majority of these being grades 1 or 2 in severity.
    - The most common hematologic treatment-emergent adverse events were thrombocytopenia (42%), neutropenia (24%), and anemia (20%), which were primarily grades 3 or 4 in severity.
    - Pancreatitis and pneumonia were the most common non-hematologic treatment-emergent serious adverse events (5% each), followed by abdominal pain (4%), myocardial infarction (3%), congestive heart failure (3%), atrial fibrillation (3%), and pyrexia (3%). The most common hematologic serious adverse events were anemia, febrile neutropenia, and thrombocytopenia (3% each).

41. On December 10, 2012, the Company issued a press release announcing long-term molecular response data on Ponatinib. The press release stated the following in relevant part:

The studies now show that 51 percent of chronic-phase CML patients in the Phase 1 trial achieved a major molecular response (MMR) with a median follow-up of 30 months, and 34 percent of chronic-phase patients achieved MMR in the PACE trial with a median follow-up of 15 months.

* * *

Molecular response is a measurement of blood levels of the transcript product of the BCR-ABL oncogene. MMR is defined as a value less than or equal to 0.1% on the accepted International Scale. All patient samples were evaluated for molecular response at a single central laboratory (Molecular MD) using a standardized assay. MMR is a secondary efficacy endpoint for chronic-phase CML patients in ARIAD's Phase 1 and pivotal Phase 2 PACE trials of ponatinib.

**Phase 1 Trial MMR Rates in Chronic-Phase CML Patients**

The ongoing Phase 1 dose-escalation study of ponatinib enrolled 81 patients with resistant or refractory hematologic cancers, including 43 patients with chronic-phase CML. Sixty-one percent of the chronic-phase CML patients in this study had failed at least three prior tyrosine kinase inhibitors (TKI).

- With a median follow-up of 30 months, 51 percent (22 of 43) of patients with chronic-phase CML enrolled in the study achieved MMR, including 75 percent (9 of 12) who had the T315I mutation, which is the most common mutation among resistant patients.
- The median time to MMR was 5.6 months, and the median duration of MMR in chronic-phase CML has not yet been reached. At the time of analysis, 21 of 22 patients who achieved MMR remained in the study and continued to receive ponatinib.
- Molecular response rates increased over time with nine percent (4 of 43) of chronic-phase CML patients achieving MMR by 3 months and 51 percent (22 of 43) achieving MMR overall. Patients continued to achieve MMRs after 12 months of follow-up.
- Thirty-three percent (14 of 43) of chronic-phase CML patients achieved MR4 (4-log reduction in BCR-ABL transcripts).
- The most common non-hematologic treatment-related adverse events in all patients in this trial included rash (42%), arthralgia (20%), increased lipase (20%), fatigue (19%) and dry skin (19%), with the majority of these being grades 1 or 2 in severity. The most common hematologic treatment-related adverse events included thrombocytopenia (34%), neutropenia (14%) and anemia (12%), with thrombocytopenia and neutropenia being primarily grades 3 or 4 in severity.

**PACE Trial MMR Rates in Chronic-Phase CML Patients**

The ongoing pivotal Phase 2 PACE trial enrolled 449 patients with chronic myeloid leukemia (CML) or Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL), who are resistant or intolerant to dasatinib or nilotinib or who have the T315I mutation.

- With a median follow up of 15 months, 34 percent (91 of 267) of chronic-phase CML patients achieved MMR; the reported prior MMR rate to their most recent TKI was three percent.

- Fifteen percent (39 of 267) of patients achieved a 4.5-log reduction of BCR-ABL transcripts (MR4.5).
- Fifty-three percent (10 of 19) of chronic-phase patients who failed only one prior approved TKI achieved MMR with ponatinib.
- The median time to MMR among responders was 6 months. MMR was durable with 81 percent of patients estimated to remain in MMR at 12 months (by Kaplan-Meier analysis). Median duration of MMR among chronic-phase CML patients has not yet been reached.
- The most common non-hematologic treatment-emergent adverse events in all patients in the PACE trial included rash (38%), abdominal pain (38%), headache (35%), dry skin (35%), and constipation (34%), with the majority of these being grades 1 or 2 in severity.
- The most common hematologic treatment-emergent adverse events were thrombocytopenia (42%), neutropenia (24%), and anemia (20%), which were primarily grades 3 or 4 in severity.
- Pancreatitis and pneumonia were the most common non-hematologic treatment-emergent serious adverse events (5% each), followed by abdominal pain (4%), myocardial infarction (3%), congestive heart failure (3%), atrial fibrillation (3%), and pyrexia (3%). The most common hematologic serious adverse events were anemia, febrile neutropenia, and thrombocytopenia (3% each).

42. On December 11, 2012, the Company issued a press release announcing 12-month data from pivotal PACE Trial of Ponatinib in heavily pretreated patients with advanced-phase CML and Ph+ ALL. The press release stated the following in relevant:

> The study now shows that 57 percent of accelerated-phase CML patients in the trial, including 50 percent of patients with the T315I mutation, achieved a major hematologic response (MaHR), the primary end-point for patients with advanced disease in the trial.
>
> * * *
>
> "Patients with advanced forms of Philadelphia chromosome-positive leukemia and those who have failed currently available therapy have limited treatment options available to them," said Hagop M. Kantarjian, M.D., chairman and professor, Department of Leukemia, University of Texas M.D. Anderson Cancer Center. "The overall prognosis is poor for patients with advanced disease."
>
> "The pivotal PACE trial data show that ponatinib has robust activity in heavily pretreated patients with accelerated phase CML, more than doubling their reported best prior responses to available TKI therapy," he added. "What is equally striking is that the median time to achieve a response to ponatinib among accelerated phase patients was only three weeks and that the median duration of major hematologic response in these patients is one year."

- ***Trial Design***

  - Efficacy data were reported at ASH on 444 treated patients in six pre-specified cohorts at 45 mg of ponatinib administered orally once daily, including 177 treated patients with advanced disease (*i.e.,* accelerated and blast phase CML and Ph+ ALL).
  - Sixty percent of accelerated phase CML patients and 53 percent of blast-phase CML and Ph+ ALL patients in the trial had received three or more tyrosine kinase inhibitors (TKI) prior to enrollment.

  - Advanced disease patients had a blood test approximately every month for determination of hematologic response and a bone-marrow assessment approximately every two months for determination of cytogenetic response.

***

- ***Safety profile (N=449)***

  - The most common non-hematologic treatment-emergent adverse events across all patients in the PACE trial included rash (in 38% of patients), abdominal pain (38%), headache (35%), dry skin (35%), and constipation (34%), with the majority of these being grades 1 or 2 in severity.
  - The most common hematologic treatment-emergent adverse events were thrombocytopenia (42%), neutropenia (24%), and anemia (20%), which were primarily grades 3 or 4 in severity.
  - Pancreatitis and pneumonia were the most common non-hematologic treatment-emergent serious adverse events (5% each), followed by abdominal pain (4%), myocardial infarction (3%), congestive heart failure (3%), atrial fibrillation (3%), and pyrexia (3%). The most common hematologic serious adverse events were anemia, febrile neutropenia, and thrombocytopenia (3% each).

43. On December 14, 2012, the Company issued a press release announcing that the FDA granted accelerated approval of Iclusig (ponatinib) for patients with CML and Ph+ ALL resistant or intolerant to prior Tyrosine Kinase Inhibitor Therapy. The press release stated the following in relevant part:

> The FDA approval of Iclusig was based on results from the pivotal Phase 2 PACE (Ponatinib Ph+ ALL and CML Evaluation) trial in patients with CML or Ph+ ALL who were resistant or intolerant to prior TKI therapy, or who had the T315I

mutation of BCR-ABL. Iclusig had robust anti-leukemic activity, with 54 percent of chronic-phase CML patients, including 70 percent of patients with the T315I mutation, achieving a major cytogenetic response (MCyR) – the primary endpoint of the PACE trial for chronic-phase patients.

In patients with advanced disease, 52 percent of accelerated-phase CML patients, 31 percent of blast-phase CML patients and 41 percent of Ph+ ALL patients achieved a major hematologic response (MaHR) to Iclusig. MaHR was the primary endpoint in the trial for patients with advanced disease.

* * *

**Important Safety Information**

Cardiovascular, cerebrovascular, and peripheral vascular thrombosis, including fatal myocardial infarction and stroke have occurred in Iclusig-treated patients. Serious arterial thrombosis occurred in 8% of Iclusig-treated patients. Interrupt and consider discontinuation of Iclusig in patients who develop arterial thrombotic events.

Hepatotoxicity, liver failure and death have occurred in Iclusig-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Iclusig for hepatotoxicity.

44. On March 1, 2013, the Company filed an annual report with the SEC on a Form 10-K for the fourth quarter and year ended December 31, 2012 which was signed by, among others, Defendants Berger and Fitzgerald. In addition, the Form 10-K contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting:

45. The 10-K represented the following in relevant part concerning Ponatinib:

The FDA approval of Iclusig was based on results from the pivotal Phase 2 PACE ( **P** onatinib Ph+ **A** LL and **C** ML **E** valuation) trial in patients with CML or Ph+ ALL who were resistant or intolerant to prior TKI therapy, or who had the T315I mutation of BCR-ABL. Iclusig had robust anti-leukemic activity, with 54 percent of chronic-phase CML patients, including 70 percent of patients with the T315I mutation, achieving a major cytogenetic response, or MCyR, which was the primary endpoint of the PACE trial for chronic-phase patients. A MCyR means that 35 percent or less of the cells in a patient's bone marrow test positive for the

> Philadelphia chromosome. In patients with advanced disease, 52 percent of accelerated-phase CML patients, 31 percent of blast-phase CML patients and 41 percent of Ph+ ALL patients achieved a major hematologic response, or MaHR, to Iclusig. MaHR was the primary endpoint in the trial for patients with advanced disease. A MaHR, as measured through the counting of white blood cells in blood and bone marrow, means that either a complete hematologic response has occurred or there is no evidence of leukemia. The most common non-hematologic adverse reactions reported (greater than or equal to 20 percent) were hypertension, rash, abdominal pain, fatigue, headache, dry skin, constipation, arthralgia, nausea, and pyrexia. Hematologic adverse reactions included thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia.
>
> The full prescribing information for Iclusig includes a boxed warning specifying that arterial thrombosis and hepatotoxicity have occurred in some patients during clinical trials of Iclusig. Cardiovascular, cerebrovascular, and peripheral vascular thrombosis, including fatal myocardial infarction and stroke, have occurred in Iclusig-treated patients. Serious arterial thrombosis occurred in 8 percent of Iclusig-treated patients. In addition, hepatotoxicity, liver failure and death have occurred in Iclusig-treated patients.

46. On May 7, 2013, the Company announced financial results for its first quarter ended March 31, 2013 and provided development progress relating to ponatinib. For the quarter, the Company reported $6.4 million of net sales for Iclusig, net loss of $64.7 million, or $0.36 per share.

47. On May 7, 2013, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended March 31, 2013, which was signed by Defendants Berger and Fitzgerald. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

48. On June 1, 2013, the Company issued a press release presenting analysis of Cardiovascular Risk Profile of Patients from Pivotal PACE Trial of Iclusig® (Ponatinib). The press release stated the following in relevant part:

Serious arterial thrombotic (AT) events can be a complication of BCR-ABL tyrosine kinase inhibitor (TKI) therapy in Ph+ leukemias. In the single-arm, PACE trial, serious AT events, including cardiovascular, cerebrovascular and peripheral vascular events, occurred in 34 of 449 patients (8%). This analysis showed that patients who experienced serious ATs while on study more commonly had a history of pre-existing cardiac disease and a higher prevalence of baseline cardiovascular risk factors prior to enrollment than in those patients who did not experience these events.

* * *

Of 34 patients with serious AT events reported in the PACE trial, 21 had cardiovascular events and 14 had cerebrovascular or peripheral vascular events. Pre-existing cardiac disease was present in 15 of 21 patients (71%) who had cardiovascular events and 6 of 14 patients (43%) who had cerebrovascular or peripheral vascular events on study. Further, 30 patients (88%) had at least one pre-existing cardiovascular risk factor, 14 patients (41%) had pre-existing ischemic cardiac disease, and 19 patients (56%) were at least 65 years of age.

"Although uncommon, cardiovascular events have been reported in patients with Ph+ leukemias treated with BCR-ABL TKIs," said H. Jean Khoury, M.D., professor of hematology and medical oncology, and director of the Division of Hematology of the Winship Cancer Institute at Emory University. "Patients in the PACE trial were heavily pretreated with multiple prior TKIs. This analysis shows that patients who experienced serious arterial thrombotic events generally were older, had a more prolonged duration of leukemia since original diagnosis, had one or more cardiovascular risk factors prior to entry in the trial and had a high prevalence of pre-existing cardiac and ischemic diseases."

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**Summary of Characteristics and Clinical Profile of Patients with Serious AT Events**

- Patients with serious AT events had significantly higher incidences of pre-existing diabetes (44% *vs.* 14%) and hypertension (82% *vs.* 51%) than patients who did not experience these events. Almost all patients who had cerebrovascular or peripheral vascular events while on study had hypertension at baseline.
- Differences in demographics, medical history and previous therapy also distinguished the population experiencing serious AT events. History of ischemic cardiac disease (41% *vs.* 10%) and age of at least 65 years (56% *vs.* 33%) were significantly greater in those with serious AT events than in those without. The population also had a significantly longer duration of prior TKI therapy (6.3 *vs.* 4.9 years) and significantly longer duration of prior nilotinib therapy (1.8 *vs.* 1.2 years).

- Patients from the serious AT group were exposed to comparable dose intensity of ponatinib when compared to those without serious AT events. The median time to onset of serious AT events was approximately six months. Blood pressure increased by one or two grades during the trial in 59% of patients who experienced serious AT events.
- Patients were managed with dose interruption and dose modification comparably in patients with and without serious AT events. In more than one-third of patients with serious ATs, there was no modification to ponatinib dosing. Discontinuation rates among patients with serious AT events were comparable to the overall discontinuation rates for the study.
- Anti-leukemic response to Iclusig was similar in patients with serious AT events as compared to those without (chronic-phase CML, 73% *vs.* 52%). Sixteen of 22 patients with serious AT events (73 %) achieved major cytogenetic response, and nine of 22 (41 %) had a major molecular response.

"This analysis is important as we consider the patient population now receiving Iclusig after becoming resistant or intolerant to prior TKI therapy and determine how to best treat patients with prior cardiovascular history or risk factors," said Frank G. Haluska, M.D., Ph.D., senior vice president, clinical research and development and chief medical officer of ARIAD. "This analysis also showed that these patients can be managed with standard dose adjustments while maintaining clinical benefit from treatment. In Philadelphia-positive leukemia patients with predisposing factors or co-morbidities, physicians should pay close attention to management of hypertension and diabetes."

49. On August 7, 2013, the Company announced financial results for its first quarter ended June 30, 2013 and provided development progress. For the quarter, the Company reported $13.9 million in net sales for Iclusig, and a net loss of $69 million, or $0.37 per share.

50. On August 9, 2013, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended June 30, 2013 which was signed by Defendants Berger and Fitzgerald. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Berger and Fitzgerald, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

51. The statements referenced in ¶¶ 20-50 above were materially false and/or misleading because they represented that the Company's leukemia drug Iclusig (ponatinib),

based on its clinical data from its pivotal PACE trial of Iclusig was safe and effective, without serious adverse events such as serious arterial thrombotic and cardiovascular events.

**THE TRUTH IS REVEALED**

52. On October 9, 2013, the Company disclosed changes in the clinical development program of Iclusig, which included adverse information regarding the results of the PACE trial. Specifically, the Company disclosed that serious arterial thrombosis occurred in a staggering 11.8% of Iclusig-treated patients, and that 6.2% of the patients had cerebrovascular events. The Company stated, in relevant part:

> ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) today announced results of its review of updated clinical data from the pivotal PACE trial of Iclusig® (ponatinib) and actions that it is taking following consultations with the U.S. Food and Drug Administration (FDA).
>
> - With a median follow up of 24 months, serious arterial thrombosis occurred in 11.8% of Iclusig-treated patients: cardiovascular events 6.2%, cerebrovascular events 4.0% and peripheral vascular events 3.6% (some patients had more than one type of event). This compares to 8.0% after 11 months of follow up reflected in the current U.S. prescribing information.
> - At 24 months, serious venous occlusion occurred in 2.9% of Iclusig-treated patients, compared to 2.2% in the current U.S. prescribing information.
> - The incidence rate of the arterial thrombotic events when normalized to duration of treatment exposure has not increased (10.0 events/100 patient-years in the original analysis and 9.6 events/100 patient-years in the current analysis).
> - Non-serious and serious arterial and venous adverse events combined occurred in approximately 20% of Iclusig-treated patients.
>
> The Company is implementing the following actions in its Iclusig clinical development program:
>
> - Patient enrollment in all clinical studies of Iclusig is being paused, and subject to agreement with the FDA, will be resumed with anticipated changes in dose and other modifications. In concert with this action, the FDA placed a partial clinical hold on all new patient enrollment in clinical trials of Iclusig.
> - Patients who are currently receiving Iclusig in clinical trials will continue on therapy. Reductions in Iclusig dose from 45 mg daily will be implemented on a trial-by-trial basis for patients whose Iclusig treatment is ongoing.
> - The dose of Iclusig in patients who are currently enrolled in the EPIC trial will be reduced to 30 mg daily unless they have achieved a major molecular response or reach one in the future, in which case the dose will be further reduced to 15 mg

daily. The Data Monitoring Committee of the EPIC trial has endorsed these changes.

- The eligibility criteria for Iclusig clinical trials will be modified to exclude patients who have experienced prior arterial thrombosis resulting in heart attack or stroke.

The PACE trial data demonstrate continued efficacy after dose reduction. Of 270 chronic-phase patients in the pivotal study, 190 patients dose reduced to either 30 mg or 15 mg. Of 110 (58%) patients who initially achieved a major cytogenetic response (MCyR), over 90% of these patients maintained this response after a median follow up of 19 months, despite dose reduction. Of 35 patients who achieved a MCyR and subsequently were reduced to 15 mg, all but 2 patients maintained the response.

53. On this news, ARIAD shares declined $11.31 per share or nearly 66%, to close at $5.83 per share on October 9, 2013.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired ARIAD securities during the Class Period (the "Class"); and were damaged thereby. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, ARIAD securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by ARIAD or its transfer agent and may be notified

of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

56. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

57. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of ARIAD;
- whether the Individual Defendants caused ARIAD to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of ARIAD securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

59. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

60. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- ARIAD securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold ARIAD securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

61. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

**COUNT I**

**(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)**

62. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

63. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

64. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue 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; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of ARIAD securities; and (iii) cause Plaintiff and other members of the Class to purchase ARIAD securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

65. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for ARIAD securities and options. Such reports, filings, releases and

statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about ARIAD's finances and business prospects.

66. By virtue of their positions at ARIAD, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

67. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of ARIAD, the Individual Defendants had knowledge of the details of ARIAD's internal affairs.

68. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of ARIAD. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to ARIAD's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of ARIAD securities was artificially inflated throughout the Class Period. In

ignorance of the adverse facts concerning ARIAD's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased ARIAD securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

69. During the Class Period, ARIAD securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of ARIAD securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of ARIAD securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of ARIAD securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

70. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

71. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period, upon the disclosure that the Company

had disseminated false financial statements to the investing public related to its prospects for FDA approval.

**COUNT II**

**(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)**

72. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

73. During the Class Period, the Individual Defendants participated in the operation and management of ARIAD, and conducted and participated, directly and indirectly, in the conduct of ARIAD's business affairs. Because of their senior positions, they knew the adverse non-public information regarding ARIAD.

74. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to ARIAD's financial condition and results of operations, and to correct promptly any public statements issued by ARIAD which had become materially false or misleading.

75. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which ARIAD disseminated in the marketplace during the Class Period concerning ARIAD's financial prospects. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause ARIAD to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of ARIAD within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of ARIAD securities.

76. Each of the Individual Defendants, therefore, acted as a controlling person of ARIAD. By reason of their senior management positions and/or being directors of ARIAD, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, ARIAD to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of ARIAD and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

77. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by ARIAD.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

## DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: October 10, 2013