

# Incyte and ARIAD Announce Agreement for Incyte to Acquire ARIAD's European Operations and In-license Iclusig® (ponatinib) in Europe

May 9, 2016

- Incyte to Accelerate the Expansion of its European Organization to Optimize the Potential of Future Product Launches in Europe
- ARIAD to Receive \$140 Million Upfront Payment, Plus Tiered Royalties on European Sales of Iclusig and Potential Milestones on Future Indications for Iclusig

WILMINGTON, Del. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 9, 2016-- Incyte Corporation (Nasdaq:INCY) and ARIAD Pharmaceuticals, Inc. (Nasdaq:ARIA) today announced the entry into a definitive agreement for Incyte to acquire ARIAD's European operations. At the close of the transaction, the companies will also enter into a license agreement whereby Incyte will obtain an exclusive license to develop and commercialize Iclusig<sup>®</sup> (ponatinib) in Europe and other select countries.

This Smart News Release features multimedia. View the full release here: http://www.businesswire.com/news/home/20160509005515/en/

The planned acquisition of a fully-integrated and established pan-European team of 125 employees, including medical, sales and marketing personnel, will further Incyte's strategic plan and accelerate the establishment of its operations in Europe, helping to optimize clinical development and maximize the potential of future European launches for Incyte's portfolio of products in development.

The agreement to divest its European operations and out-license Iclusig in Europe will enable ARIAD to focus its promotion of Iclusig on the highly valuable U.S. market, while strengthening its financial position and maintaining important optionality through a potential buy-back provision for the Iclusig license rights in the event of a change-in-control of ARIAD, as described further below.

Under the terms of the license agreement, Incyte will receive an exclusive license to develop and commercialize Iclusig, the only approved BCR-ABL inhibitor with activity against the T315I mutation, throughout Europe and in other select countries. Iclusig is approved in Europe for the treatment of patients with chronic myeloid leukemia (CML) and Philadelphia-positive (Ph+) acute lymphoblastic leukemia (ALL) who are resistant to or intolerant of certain second generation BCR-ABL inhibitors and all patients who have the T315I mutation.

"The acquisition of ARIAD's European operations is a unique and strategic opportunity for Incyte, which will further establish our medical and commercial footprint in Europe," said Hervé Hoppenot, chief executive officer of Incyte. "Adding the ARIAD team's experience, talent, resources and relationships to our existing European organization accelerates our planned global expansion and leaves us well-positioned to maximize the potential future European launches from our rich development portfolio."

"The decision to divest our European operations and out-license the commercial rights to Iclusig in Europe is one of the key outcomes of our ongoing strategic review," stated Paris Panayiotopoulos, president and chief executive officer of ARIAD. "We are delighted to have Incyte as a committed partner to continue Iclusig's strong revenue growth in Europe, while significantly strengthening our financial position and maintaining future strategic optionality with a potential buy-back of Iclusig."

# Terms of the Agreements

Pursuant to the terms of a share purchase agreement (the "SPA"), Incyte will acquire all shares of ARIAD Pharmaceuticals (Luxembourg) S.a.r.l., the parent company of ARIAD's European subsidiaries responsible for the commercialization of Iclusig in the licensed territory, for a payment to ARIAD of \$140 million that will be funded by Incyte through available cash on hand.

In addition to the SPA, the parties have agreed to enter into a license agreement (the "License Agreement"), upon the closing of the SPA, pursuant to which Incyte will be granted an exclusive license to develop and commercialize Iclusig in the European Union and 22 other countries, including Switzerland, Norway, Turkey, Israel and Russia. ARIAD will be entitled to receive tiered royalties of between 32 and 50 percent on net sales of Iclusig in the territory and up to \$135 million in potential development and regulatory milestones for Iclusig in new oncology indications in the territory. ARIAD may also become eligible to receive additional milestones for non-oncology indications, if approved, in the territory. Incyte has also agreed to fund a portion of the ongoing clinical development of Iclusig in ARIAD's OPTIC and OPTIC-2L clinical trials through cost-sharing payments of up to \$7 million in each of 2016 and 2017.

The terms of the License Agreement also include an option for an acquirer of ARIAD to buy back the rights to Iclusig by repaying the upfront and milestone payments, plus paying an additional amount based on Iclusig sales during the previous 12 months and royalties of 20 to 25 percent on sales for the remaining royalty term. The buy-back provision cannot be exercised before two years or after six years from the closing of this transaction, and includes a transition period of up to one year.

The transaction is expected to close on or about June 1, 2016, subject to customary closing conditions, and is expected to reduce ARIAD's 2017 annual operating expenses by approximately \$65 million. The transaction is expected to be earnings accretive for Incyte in 2018.

Both Incyte and ARIAD expect to file additional disclosure documents with the Securities and Exchange Commission related to this transaction.

# ARIAD Investor Conference Call Today at 8:30 a.m. EDT

ARIAD will hold a live webcast and conference call regarding the transaction with Incyte this morning at 8:30 a.m. EDT. The live webcast can be accessed by visiting the investor relations section of ARIAD's website at <a href="http://investor.ariad.com">http://investor.ariad.com</a>. The call can be accessed by dialing 844-249-9386 (domestic) or 270-823-1534 (international) five minutes prior to the start time and providing the pass code 7492679. A replay of the call will be available on the ARIAD website approximately two hours after completion of the call and will be archived for three weeks.

## Incyte Conference Call and Webcast Today at 10:00 a.m. EDT

Incyte will hold its 2016 first-quarter financial results conference call and webcast this morning at 10:00 a.m. EDT. To access the conference call, please dial 877-407-9221 for domestic callers or 201-689-8597 for international callers. When prompted, provide the conference identification number, 13628695.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference identification number, 13628695.

The conference call will also be webcast live and can be accessed at www.incyte.com in the Investors section under "Events and Presentations".

## About CML and Ph+ ALL

CML is a cancer of the white blood cells that is diagnosed in approximately 7,000 patients each year in Europe<sup>1</sup>. CML is characterized by an excessive and unregulated production of white blood cells by the bone marrow due to a genetic abnormality that produces the BCR-ABL protein. After a chronic phase of production of too many white blood cells, CML typically evolves to the more aggressive phases referred to as accelerated phase and blast crisis. Ph+ ALL is a subtype of acute lymphoblastic leukemia that carries the Ph+ chromosome that produces BCR-ABL. It has a more aggressive course than CML and is often treated with a combination of chemotherapy and tyrosine kinase inhibitors. The BCR-ABL protein is expressed in both of these diseases.

# About Iclusig<sup>®</sup> (ponatinib) tablets

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig was designed using ARIAD's computational and structure-based drug-design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

Iclusig is approved in the U.S., EU, Australia, Switzerland, Israel and Canada.

In the U.S., Iclusig is a kinase inhibitor indicated for the:

• Treatment of adult patients with T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315Ipositive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

• Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.

These indications are based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with Iclusig.

IMPORTANT SAFETY INFORMATION, INCLUDING THE BOXED WARNING

# WARNING: VASCULAR OCCLUSION, HEART FAILURE, and HEPATOTOXICITY

See full prescribing information for complete boxed warning

• Vascular Occlusion: Arterial and venous thrombosis and occlusions have occurred in at least 27% of Iclusig treated patients, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors, including patients less than 50 years old, experienced these events. Monitor for evidence of thromboembolism and vascular occlusion. Interrupt or stop Iclusig immediately for vascular occlusion. A benefit risk consideration should guide a decision to restart Iclusig therapy.

• Heart Failure, including fatalities, occurred in 8% of Iclusig-treated patients. Monitor cardiac function. Interrupt or stop Iclusig for new or worsening heart failure.

• Hepatotoxicity, liver failure and death have occurred in Iclusig-treated patients. Monitor hepatic function. Interrupt Iclusig if hepatotoxicity is suspected.

Please see the full U.S. Prescribing Information for Iclusig, including the Boxed Warning, for additional important safety information.

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

<u>Click here</u> to view the Iclusig EU Summary of Medicinal Product Characteristics. <u>Click here</u> to view the EU Dear Healthcare Provider Letter (PDF).

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at <a href="http://www.incyte.com">www.incyte.com</a>.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

## About ARIAD

ARIAD Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts and Lausanne, Switzerland, is an orphan oncology company focused on transforming the lives of cancer patients with breakthrough medicines. ARIAD is working on new medicines to advance the treatment of various forms of chronic and acute leukemia, lung cancer and other difficult-to-treat orphan cancers. ARIAD utilizes computational and structural approaches to design small-molecule drugs that overcome resistance to existing cancer medicines. For additional information, visit <a href="http://www.ariad.com">http://www.ariad.com</a> or follow ARIAD on Twitter (@ARIADPharm).

# Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether and when the planned acquisition of ARIAD's European operations and of the rights for Iclusig will close; whether and when this planned acquisition will effectively advance Incyte's European organization, maximize any future European product launches or be accretive to Incyte's earnings; and whether and when any of Incyte's product candidates will be approved in Europe. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining approval for this planned acquisition; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors; unanticipated delays; our ability to compete against parties with greater financial or other resources; greater than expected expenses; and such other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2015. Incyte disclaims any intent or obligation to update these forward-looking statements.

#### **ARIAD Forward-Looking Statements**

This press release contains forward-looking statements, each of which are gualified in their entirety by this cautionary statement. Any statements contained herein which do not describe historical facts, including, but not limited to statements related to the expected completion of the proposed transaction with Incyte and the closing date of the transaction, the expected benefits to ARIAD of the proposed transaction with Incyte, the impact of the transaction on ARIAD's financial position and operating expenses, and ARIAD's plans following the completion of the transaction, are forwardlooking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to, our ongoing strategic review, our ability to successfully commercialize and generate profits from sales of Iclusig and our product candidates, if approved; competition from alternative therapies; our ability to meet anticipated clinical trial commencement, enrollment and completion dates and regulatory filing dates for our products and product candidates and to move new development candidates into the clinic; our ability to execute on our key corporate initiatives; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory and pricing and reimbursement approvals to market our products; our reliance on the performance of third-party manufacturers and specialty pharmacies for the supply and distribution of our products and product candidates; the occurrence of adverse safety events with our products and product candidates; the costs associated with our research, development, manufacturing, commercialization and other activities; the conduct, timing and results of preclinical and clinical studies of our products and product candidates, including that preclinical data and early-stage clinical data may not be replicated in later-stage clinical studies; the adequacy of our capital resources and the availability of additional funding; the ability to satisfy our contractual obligations, including under our leases, convertible debt and royalty financing agreements; patent protection and third-party intellectual property claims; litigation; our operations in foreign countries; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other risk factors detailed in our public filings with the U.S. Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release and we undertake no obligation to update or revise any of these statements to reflect events or circumstances occurring after this press release. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

<sup>1</sup> Rohrbacher M, Hasford J. Epidemiology of chronic myeloid leukaemia (CML). <u>Best Pract Res Clin Haematol</u>. 2009 Sep;22(3):295-302. Based on current estimate of population of Europe (738,199,000 in 2010).

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