Incyte Reports First-Quarter 2013 Financial Results; Updates Shareholders on Key Clinical Programs

May 2, 2013

- $48.3 million of first-quarter 2013 net product revenues from Jakafi® (ruxolitinib)

Conference Call Scheduled Today at 8:30 a.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--May. 2, 2013-- Incyte Corporation (Nasdaq: INCY) today reported first-quarter 2013 financial results, including revenue from Jakafi® (ruxolitinib), which is approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis (MF). The Company also updated information about key clinical programs.

“We continue to see solid growth for Jakafi, which means that more patients are experiencing the benefits of the first FDA-approved treatment for intermediate or high-risk myelofibrosis,” stated Paul A. Friedman, M.D., Incyte’s President and Chief Executive Officer. “Additionally, as we gain important visibility into several mid-stage trials, we continue to broaden the scope of our R&D efforts, as evidenced by the introduction of a second JAK1 inhibitor into clinical development.”

First-Quarter 2013 Financial Results

Cash Position

As of March 31, 2013, cash, cash equivalents and marketable securities totaled $270.2 million compared to $228.4 million as of December 31, 2012.

Product Revenues and Royalties

For the quarter ended March 31, 2013, net product revenues of Jakafi were $48.3 million as compared to $19.3 million for the comparable period in 2012. Product royalties from sales of Jakavi® outside the United States by our collaboration partner, Novartis, for the quarter ended March 31, 2013, were $5.9 million; there were no product royalties earned in the comparable period in 2012.

Total Revenues

Total revenues for the quarter ended March 31, 2013, were $71.1 million as compared to $36.2 million for the same period in 2012. The increase in total revenues from the first quarter of 2012 to the first quarter of 2013 was primarily related to increased Jakafi product revenue and $5.9 million of Jakavi product royalties from Novartis.

Net Loss

Quarter Ended March 31, 2013

Net loss for the quarter ended March 31, 2013, was $15.7 million, or $0.12 per basic and diluted share, as compared to a net loss of $45.4 million, or $0.36 per basic and diluted share, for the same period in 2012. The decrease in net loss in the first quarter of 2013 from the first quarter of 2012 is primarily due to increased Jakafi product revenue and $5.9 million of Jakavi product royalties from Novartis.

Non-Cash Stock Option Expense

Included in net loss for the quarter ended March 31, 2013, was $9.2 million of non-cash expense related to employee stock options, of which $6.5 million was included in research and development expenses and $2.7 million was included in selling, general and administrative expenses. Included in net loss for the quarter ended March 31, 2012, was $9.9 million of non-cash expense related to employee stock options, of which $6.7 million was included in research and development expenses and $3.2 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter ended March 31, 2013, were $52.8 million, as compared to $49.0 million for the same period in 2012. The increase in research and development expenses for the quarter ended March 31, 2013, compared to the prior year period was due to the advancement of the Company’s pipeline. The Company expects its research and development expenses to vary from period to period, primarily due to the timing of its clinical development activities.

Selling, general and administrative expenses for the quarter ended March 31, 2013, were $22.3 million, as compared to $21.4 million for the same period in 2012. Increased selling, general and administrative expenses for the quarter ended March 31, 2013, compared to the comparable prior year period reflected additional costs related to the commercialization of Jakafi.

Interest Expense

Interest expense for the quarter ended March 31, 2013, was $11.7 million as compared to $11.3 million for the comparable period in 2012. Included in interest expense for the quarter ended March 31, 2013, was $7.0 million of non-cash charges to amortize the discount on the Company’s 4.75% Convertible Senior Notes due 2015, as compared to $6.5 million for the same period in 2012. Increased interest expense is primarily attributable to the accretion of the discount related to the 4.75% Convertible Senior Notes.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

Results of RESPONSE, a study in partnership with Novartis to evaluate ruxolitinib in patients with polycythemia vera (PV), are expected in early 2014. Completion of this pivotal trial, if positive, should allow for the filing of a supplemental new drug application submission in the first half of 2014. The RELIEF trial continues to recruit, and when completed, we plan to submit the results to support labeling claims on symptomatic benefit in PV.

A randomized Phase II trial of ruxolitinib in combination with capecitabine is ongoing with approximately 135 patients with recurrent or treatment refractory metastatic pancreatic cancer (the RECAP trial). The primary endpoint is overall survival, with results expected in the second half of 2013.

An open-label Phase I trial of ruxolitinib in combination with chemotherapy in patients with advanced solid tumors was initiated in April 2013. The primary endpoint is identification of the maximum tolerated dose of ruxolitinib in combination with gemcitabine or in combination with gemcitabine and nab-paclitaxel. The estimated completion date for the trial is the second half of 2014.

Multiple investigator-sponsored trials evaluating ruxolitinib are ongoing, including a Phase I/II trial in adults with advanced hematologic malignancies (acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome and chronic myelogenous leukemia); a Phase I/II trial in patients with relapsed or refractory acute leukemia; a Phase II trial in patients with lymphoma; and two Phase II trials in patients with breast cancer.

Baricitinib - a JAK1 and JAK2 Inhibitor

Lilly, our strategic partner for our second JAK1 and JAK 2 inhibitor, baricitinib, has several programs underway for this compound, including four Phase III trials in patients with rheumatoid arthritis, a Phase II trial in patients with moderate to severe psoriasis, and a Phase II trial in patients with diabetic nephropathy.

INC280 (formerly INCB28060) – a c-MET Inhibitor

This compound is licensed to Novartis as part of the Incyte-Novartis collaboration, and further development will be conducted by Novartis, which recently initiated a Phase II clinical trial evaluating INC280 as monotherapy in patients with advanced hepatocellular carcinoma.

INCB24360 – an IDO1 Inhibitor

INCB24360 is currently in Phase I/II clinical development for metastatic melanoma in combination with ipilimumab and as monotherapy for ovarian cancer.

INCB39110 – a JAK1 Inhibitor

Three proof-of-concept studies evaluating INCB39110 in patients with myelofibrosis, psoriasis and rheumatoid arthritis are underway, with preliminary results expected in the second half of 2013. The results of these studies are expected to inform us as to the most appropriate indications for further development.

INCB47986 – a JAK1 Inhibitor

A second JAK1 inhibitor, INCB47986, recently entered Phase I clinical development.

Conference Call Information

Incyte will hold its first-quarter 2013 financial results conference call this morning at 8:30 a.m. ET. To access the conference call, please dial 877-407-8037 for domestic callers or 201-689-8037 for international callers. When prompted, provide the conference identification number, 412369.

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, 412369.

The conference call will also be webcast live and can be accessed at www.incyte.com under Investor Relations – Events and Webcasts.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

About Jakafi

Jakafi is a prescription medicine used to treat people with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF.

Important Safety Information

- Treatment with Jakafi can cause hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia, which are each dose-related effects, with the most frequent being thrombocytopenia and anemia. A complete blood count must be performed before initiating therapy with Jakafi. Complete blood counts should be monitored as clinically indicated and dosing adjusted as required. The three most frequent non-hematologic adverse reactions were bruising, dizziness and headache

- Patients with platelet counts <200 × 10^9/L at the start of therapy are more likely to develop thrombocytopenia during treatment. Thrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi. If clinically indicated, platelet transfusions may be administered
- Patients developing anemia may require blood transfusions. Dose modifications of Jakafi for patients developing anemia may also be considered
- Neutropenia (ANC <0.5 × 10^9/L) was generally reversible and was managed by temporarily withholding Jakafi
- Patients should be assessed for the risk of developing serious bacterial, mycobacterial, fungal and viral infections. Active serious infections should have resolved before starting Jakafi. Physicians should carefully observe patients receiving Jakafi for signs and symptoms of infection (including herpes zoster) and initiate appropriate treatment promptly
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or in patients with renal or hepatic impairment *[see Dosage and Administration]*. Patients should be closely monitored and the dose titrated based on safety and efficacy
- There are no adequate and well-controlled studies of Jakafi in pregnant women. Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus
- Women taking Jakafi should not breast-feed. Discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother

For Full Prescribing Information for Jakafi, visit www.Jakafi.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements regarding expected variations in research and development expenses, our plans and expectations with respect to Jakafi® (ruxolitinib), including the potential efficacy and therapeutic and commercial value of Jakafi, our expectation of results from the RESPONSE trial evaluating ruxolitinib in PV in early 2014 and the filing of a supplemental new drug application in the first half of 2014, our plan to submit results from the RELIEF trial to support labeling claims on symptomatic benefit in PV, our expectation of results from the RECAP trial in the second half of 2013, our expectation that the Phase I trial of ruxolitinib in combination with chemotherapy in patients with advanced solid tumors will be completed in the second half of 2014 and our expectation of preliminary results from the three proof-of-concept studies evaluating INCB39110 in patients with myelofibrosis, psoriasis and rheumatoid arthritis in the second half of 2013 and these results being expected to inform us as to the most appropriate indications for further development, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of Jakafi, the acceptance of Jakafi in the marketplace, risks related to market competition, the results of further research and development, risks and uncertainties associated with sales, marketing and distribution requirements, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, risks associated with Incyte's dependence on its relationships with its collaboration partners, and 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, 2012.

Incyte disclaims any intent or obligation to update these forward-looking statements.

INCYTE CORPORATION
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2013	**2012**
Revenues:		
Product revenues, net	$ 48,289	$ 19,279
Product royalty revenues	5,909	-
Contract revenues	16,737	16,737
Other revenues	142	163
Total revenues	71,077	36,179
Costs and expenses:		
Cost of product revenues	150	11
Research and development	52,763	48,960
Selling, general and administrative	22,261	21,396

Total costs and expenses	75,174	70,367
Loss from operations	(4,097)	(34,188)
Interest and other income, net	199	52
Interest expense	(11,728)	(11,290)
Loss before income taxes	(15,626)	(45,426)
Provision for income taxes	43	-
Net loss	$(15,669)	$(45,426)
Basic and diluted net loss per share	$ (0.12)	$ (0.36)
Shares used in computing basic and diluted net loss per share	134,345	127,203

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2013	December 31, 2012
Cash, cash equivalents, and short-term marketable securities	270,179	228,418
Accounts receivable, net	28,041	70,951
Total assets	330,282	330,419
Convertible senior notes(1)	328,354	322,043
Convertible subordinated notes	9,159	9,033
Total stockholders' deficit	(163,526)	(174,957)

(1) Net of unamortized debt discount of $71.6 million and $78.0 million at March 31, 2013 and December 31, 2012, respectively.

Source: Incyte Corporation

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