Incyte Reports 2014 Third-Quarter Financial Results and Updates Shareholders on Key Clinical Programs

October 30, 2014

- *$97.8 million of 2014 third-quarter net product revenues from Jakafi® (ruxolitinib), representing 63 percent growth over the same period last year*
- *2014 guidance for Jakafi net product revenues increased to range of $350 million to $360 million, driven by continued strong growth in underlying demand*
- *Two milestone payments from Novartis earned in the third quarter, totaling $85 million*
- *Recruitment continuing across clinical development pipeline in multiple pivotal and proof-of-concept studies*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 30, 2014-- Incyte Corporation (Nasdaq: INCY) today reported 2014 third-quarter financial results, including revenue from Jakafi® (ruxolitinib). The Company highlighted the strength in Jakafi sales in the U.S. as well as the recognition of two significant milestone payments from Novartis related to Jakavi® (ruxolitinib), totaling $85 million. The Company outlined its progress in recruiting multiple clinical trials, including those investigating its JAK inhibitors in solid tumors and its IDO1 inhibitor in combination with other immuno-oncology agents. The Company also highlighted the Priority Review granted by the U.S. Food and Drug Administration (FDA) to the supplemental New Drug Application (sNDA) for ruxolitinib for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, as well as the expected release of top-line results from the first trial in the Phase III program of baricitinib in rheumatoid arthritis patients.

“The strong commercial performance of Jakafi in the U.S. speaks to the long-term potential of the product to treat patients with intermediate or high-risk myelofibrosis,” stated Hervé Hoppenot, Incyte’s President and Chief Executive Officer. “In addition, we believe we are fully prepared for the U.S. launch of ruxolitinib for patients with uncontrolled polycythemia vera, pending expected FDA approval, and are also making progress across our broad development pipeline.”

Jakafi® is approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis (MF).

2014 Third-Quarter Financial Results

Revenues

For the quarter ended September 30, 2014, net product revenues of Jakafi were $97.8 million as compared to $60.2 million for the same period in 2013, representing 63 percent growth. For the nine months ended September 30, 2014, net product revenues were $251.5 million as compared to $162.6 million for the same period in 2013, representing 55 percent growth.

The Company now expects that 2014 net product revenues from Jakafi will be in the range of $350 million to $360 million, an increase from the previous range of $330 million to $340 million. This range excludes any product royalty revenues received from the Company’s collaboration partner Novartis on sales of Jakavi® outside the United States.

For the quarter and nine months ended September 30, 2014, product royalties from sales of Jakavi® outside the United States received from Novartis were $12.1 million and $34.3 million, respectively, as compared to $8.2 million and $19.9 million, respectively, for the same periods in 2013.

For the quarter ended September 30, 2014, contract revenues were $88.2 million as compared to $16.7 million for the same period in 2013. For the nine months ended September 30, 2014, contract revenues were $101.6 million as compared to $75.2 million for the same period in 2013.

The increase in contract revenues for the quarter ended September 30, 2014 compared to the same period in 2013 relates to the $60.0 million milestone related to reimbursement of Jakavi® in Europe and the $25.0 million milestone in connection with the approval of Jakavi® in Japan in the third quarter of 2014. The increase in contract revenues for the nine months ended September 30, 2014 compared to the same period in 2013 relates to the aforementioned $85.0 million in milestones recognized in the third quarter of 2014 and the $7.0 million milestone related to our c-MET program recognized in the first quarter of 2014 compared to the $25.0 million milestone related to our c-MET program recognized in the second quarter of 2013.

For the quarter ended September 30, 2014, total revenues were $198.1 million as compared to $85.1 million for the same period in 2013. For the nine months ended September 30, 2014, total revenues were $387.5 million as compared to $257.9 million for the same period in 2013.

Non-Cash Stock Expense

Included in operating expenses for the quarter ended September 30, 2014, was $15.5 million of non-cash expense related to equity awards to our employees, of which $8.4 million was included in research and development expenses and $7.1 million was included in selling, general and administrative expenses. For the year to date, non-cash expense related to equity awards to our employees was $46.3 million, of which $25.2 million was included in research and development expenses and $21.1 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter and nine months ended September 30, 2014, were $88.5 million and $248.8 million, respectively, as compared to $71.7 million and $185.4 million, respectively, for the same periods in 2013.

The increase in research and development expenses for the quarter and nine months ended September 30, 2014, compared to the same prior year periods, was primarily due to the expansion of the Company's pipeline, which included the costs related to two Phase III trials of ruxolitinib in pancreatic cancer; Phase II trials of ruxolitinib in non-small cell lung cancer, colorectal cancer and breast cancer; a Phase II trial of INCB39110 in non-small cell lung cancer; and the Phase III program for baricitinib in rheumatoid arthritis.

Selling, general and administrative expenses for the quarter and nine months ended September 30, 2014, were $39.4 million and $117.3 million, respectively, as compared to $26.4 million and $72.0 million, respectively, for the same periods in 2013.

Increased selling, general and administrative expenses for the quarter and nine months ended September 30, 2014, compared to the same prior year periods reflected the additional costs related to the commercialization of Jakafi in MF, including the expansion in our field force, as well as preparation for the anticipated launch in polycythemia vera.

Interest Expense

Interest expense for the quarter and nine months ended September 30, 2014, was $11.5 million and $34.3 million, respectively, as compared to $7.7 million and $29.7 million, respectively, for the same periods in 2013. Included in interest expense for the quarter and nine months ended September 30, 2014, were $8.9 million and $26.6 million, respectively, of non-cash charges to amortize the discount on the Company's 4.75% Convertible Senior Notes due 2015 (2015 Notes), 0.375% Convertible Senior Notes due 2018 and 1.25% Convertible Senior Notes due 2020, as compared to $4.7 million and $17.9 million, respectively, to amortize the discount on the Company's 2015 Notes for the same periods in 2013.

Net Loss/Net Income

Net income for the quarter ended September 30, 2014, was $59.3 million, or $0.35 per basic and $0.33 per diluted share, as compared to a net loss of $22.0 million, or $0.14 per basic and diluted share, for the same period in 2013. Net loss for the nine months ended September 30, 2014, was $11.5 million, or $0.07 per basic and diluted share, as compared to a net loss of $40.3 million, or $0.28 per basic and diluted share, for the same period in 2013.

Cash and Marketable Securities Position

As of September 30, 2014, cash, cash equivalents and marketable securities totaled $532.4 million compared to $509.0 million as of December 31, 2013.

Recent Clinical Highlights

Jakafi® (ruxolitinib) – a JAK1 and JAK2 Inhibitor

Myeloproliferative Neoplasms

In July 2014 the product label for Jakafi was expanded to include overall survival data and additional safety and dosing information. This new information is based on three-year data from the two pivotal Phase III trials in myelofibrosis patients, COMFORT-I and II.

In August 2014 the FDA accepted for filing the sNDA for ruxolitinib as a potential treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. The sNDA includes results from the RESPONSE Phase III trial, which was conducted under a Special Protocol Assessment (SPA) from the FDA. The Prescription Drug User Fee Act date for the sNDA for ruxolitinib, which is under priority review, is December 5, 2014.

Solid Tumors

Two pivotal double-blind, placebo-controlled Phase III trials (JANUS 1 and JANUS 2) of ruxolitinib for advanced or metastatic pancreatic cancer have been initiated and are recruiting patients. JANUS 1 is being conducted under an SPA from the FDA. Both trials are designed to examine the safety and efficacy of ruxolitinib in pancreatic cancer patients with high levels of systemic inflammation, and data from both trials are expected in 2016.

Three additional blinded Phase II proof-of-concept trials of ruxolitinib focusing on survival in non-small cell lung cancer (NSCLC), breast cancer and colorectal cancer patients with high levels of systemic inflammation are also recruiting patients.

INCB39110 – a JAK1 Inhibitor

The clinical program to evaluate INCB39110, a selective JAK1 inhibitor, in solid tumors includes one ongoing Phase I open-label safety study in combination with gemcitabine and nab-paclitaxel in various tumor types, and two blinded proof-of-concept Phase II trials in NSCLC. The first of these, a randomized, double-blind Phase II trial of INCB39110 in combination with docetaxel, was initiated in the second quarter of 2014. The second trial, in EGFR-mutated NSCLC in combination with erlotinib, is expected to be initiated later in 2014 or early in 2015. Both Phase II trials are designed with overall survival as the primary endpoint, and will only include patients with high levels of systemic inflammation.

INCB24360 – an IDO1 Inhibitor

The Company believes that the optimal development strategy for INCB24360, its IDO1 inhibitor, is for the compound to be developed in combination with other immuno-oncology agents. A Phase I/II trial to evaluate the combination of INCB24360 and Merck's anti-PD-1 immune checkpoint inhibitor, pembrolizumab, has been initiated. This trial is recruiting patients with previously treated metastatic and recurrent NSCLC and other advanced or metastatic cancers.

A total of four clinical trial agreements have been signed to evaluate INCB24360 in combination with immune checkpoint inhibitors. As well as the agreement with Merck, the Company has signed agreements involving AstraZeneca's investigational PD-L1 inhibitor, MEDI4736, Bristol-Myers Squibb's investigational PD-1 inhibitor, nivolumab, and Genentech's investigational PD-L1 inhibitor, MPDL3280A.

INCB40093 – a PI3K-delta Inhibitor

INCB40093 is being studied as both monotherapy and in combination with the Company's JAK1 inhibitor, INCB39110, in patients with B-lymphoid malignancies.

Baricitinib – a JAK1 and JAK2 Inhibitor

The Phase III clinical program to evaluate baricitinib in patients with rheumatoid arthritis, being conducted by the Company's collaboration partner Lilly, is ongoing. The first of four Phase III trials is expected to be reported by Lilly in late 2014 or early 2015.

INC280 – a c-MET Inhibitor

Novartis is conducting a Phase II trial to evaluate INC280 as monotherapy in advanced c-MET positive hepatocellular carcinoma and a Phase II trial to evaluate INC280 in c-MET positive/EGFR-TKI-resistant NSCLC. Novartis is also conducting Phase I/II trials in c-MET dependent advanced solid malignancies.

Novartis has also announced that it has entered into a clinical collaboration with Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of INC280 in combination with Bristol-Myers Squibb's investigational PD-1 immune checkpoint inhibitor, nivolumab, in a Phase I/II trial of patients with NSCLC.

Conference Call Information

Incyte will hold its 2014 third-quarter 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, 13592296.

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, 13592296.

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, primarily for oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

About Jakafi® (ruxolitinib)

Jakafi is a prescription medicine approved by the U.S. Food and Drug Administration to treat people with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF. Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States.

Important Safety Information

Jakafi can cause serious side effects including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had liver or kidney problems, are on dialysis, or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.incyte.com, which includes a more complete discussion of the risks associated with Jakafi.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements regarding financial guidance about expected net product revenues; the Company's plans and expectations with respect to Jakafi ® (ruxolitinib), including its potential efficacy and therapeutic and commercial value; the Company's expectations regarding the FDA approval for, and launch of, ruxolitinib in uncontrolled polycythemia vera; the Company's expectation of data in 2016 from the JANUS 1 and JANUS 2 trials of ruxolitinib for advanced or metastatic pancreatic cancer; the Company's plans for INCB39110 to initiate the second Phase II trial in patients with non-small cell lung cancer later in 2014 or early in 2015; and the Company's expectation that the results from the first Phase III trial conducted by its collaboration partner Lilly

evaluating baricitinib in rheumatoid arthritis will be reported by Lilly in late 2014 or early 2015, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company'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, economic or strategic factors and technological advances, unanticipated delays, the ability of the Company to compete against parties with greater financial or other resources, risks associated with the Company's dependence on its relationships with its collaboration partners, and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2014.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Product revenues, net	$ 97,837	$ 60,201	$251,513	$162,589
Product royalty revenues	12,093	8,184	34,259	19,893
Contract revenues	88,214	16,737	101,643	75,211
Other revenues	3	1	107	182
Total revenues	198,147	85,123	387,522	257,875
Costs and expenses:				
Cost of product revenues	221	155	576	463
Research and development	88,537	71,704	248,806	185,417
Selling, general and administrative	39,446	26,447	117,320	71,956
Total costs and expenses	128,204	98,306	366,702	257,836
Income (loss) from operations	69,943	(13,183)	20,820	39
Interest and other income, net	885	385	2,410	829
Interest expense	(11,463)	(7,699)	(34,312)	(29,720)
Debt exchange expense	-	(1,491)	(265)	(11,262)
Income (loss) before income taxes	59,365	(21,988))	(11,347))	(40,114)
Provision for income taxes	72	49	191	162
Net income (loss)	$ 59,293	$(22,037)	$(11,538)	$(40,276)
Net income (loss) per share				
Basic	$ 0.35	$ (0.14)	$ (0.07)	$ (0.28)
Diluted	$ 0.33	$ (0.14)	$ (0.07)	$ (0.28)
Shares used in computing basic and diluted net income (loss) per share				
Basic	168,592	155,067	167,288	143,899
Diluted	189,046	155,067	167,288	143,899

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, 2014	December 31, 2013

(unaudited)

Cash, cash equivalents, and short-term marketable securities	$ 532,359	$ 509,004
Accounts receivable, net	109,599	35,374
Total assets	785,265	629,568
Convertible senior notes(1)	681,313	661,567
Total stockholders' deficit	(89,591)	(193,108)

(1) Net of unamortized debt discount of $160.1 million and $185.0 million at September 30, 2014 and December 31, 2013, respectively.

Source: Incyte Corporation

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