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

October 31, 2013

- *$60.2 million of third-quarter net product revenues from Jakafi, reflecting solid growth in underlying demand*
- *Top-line results from Phase II trial of ruxolitinib in patients with refractory metastatic pancreatic cancer suggest a demonstrable survival benefit in a well-defined subgroup of patients*
- *Positive Phase II data from trials of oral JAK1 inhibitor, INCB39110, in psoriasis and rheumatoid arthritis presented at recent scientific meetings*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 31, 2013-- Incyte Corporation (Nasdaq: INCY) today reported third-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 described: positive top-line results of its Phase II trial (RECAP) of ruxolitinib in patients with refractory metastatic pancreatic cancer; positive Phase II proof-of-concept data recently presented at key scientific meetings for its lead JAK1 inhibitor, INCB39110; and progress for several of its other key clinical programs.

“The growth of Jakafi remains strong, and we’re encouraged by the sustained steady rate of new prescriptions for patients with myelofibrosis and continued evidence that physicians are successfully individualizing dosing,” stated Paul A. Friedman, M.D., Incyte’s President and Chief Executive Officer. “With potential approval of ruxolitinib for use in polycythemia vera in late 2014 and recent data from the RECAP trial that suggest potential benefit in pancreatic cancer and opportunities in other solid tumors, we see several drivers to further grow revenues for our first product, while we continue to deliver promising results for other compounds in our growing pipeline.”

2013 Third-Quarter Financial Results

Cash Position

As of September 30, 2013, cash, cash equivalents and marketable securities totaled $291.2 million compared to $228.4 million as of December 31, 2012.

Revenues

Total revenues for the quarter ended September 30, 2013, were $85.1 million as compared to $60.5 million for the comparable period in 2012. Total revenues for the nine months ended September 30, 2013, were $257.9 million as compared to $183.2 million for the comparable period in 2012.

Jakafi net product revenues were $60.2 million for the quarter ended September 30, 2013, as compared to $43.7 million for the comparable period in 2012. For the nine months ended September 30, 2013, Jakafi net product revenues were $162.6 million as compared to $92.7 million for the comparable period in 2012.

Product royalties from sales of Jakavi® (ruxolitinib) outside the United States received from Novartis for the quarter and nine months ended September 30, 2013, were $8.2 million and $19.9 million, respectively; there were no product royalties earned in the comparable periods in 2012.

Also included in revenues for each of the quarters ended September 30, 2013, and September 30, 2012, were contract revenues of $16.7 million. For the nine months ended September 30, 2013, contract revenues were $75.2 million as compared to $90.2 million for the comparable period in 2012. Included in contract revenues for the nine months ended September 30, 2013, was a $25 million milestone payment received from Novartis related to our c-Met program. Included in contract revenues for the nine months ended September 30, 2012, was a $40 millionEuropean Union regulatory milestone payment received from Novartis related to Jakavi.

Net Loss

Net loss for the quarter ended September 30, 2013, was $22.0 million, or $0.14 per basic and diluted share, as compared to a net loss of $21.7 million, or $0.17 per basic and diluted share, for the same period in 2012. For the nine months ended September 30, 2013, net loss was $40.3 million, or $0.28 per basic and diluted share, as compared to a net loss of $63.1 million, or $0.49 per basic and diluted share, for the same period in 2012. Included in the net loss for the quarter and nine months ended September 30, 2013, were cash charges of $1.5 million and $11.3 million, respectively, or $0.01 and $0.08 per basic and diluted share, respectively, related to the exchange of the Company’s 4.75% Convertible Senior Notes due 2015 (4.75% Senior Notes) as described below.

Non-Cash Stock Option Expense

Non-cash expense related to employee stock options for the third quarter of 2013 was $9.5 million, of which $6.4 million was included in research and development expenses and $3.1 million was included in selling, general and administrative expenses. For the year to date, non-cash expense related to employee stock options was $28.6 million, of which $19.6 million was included in research and development expenses and $9.0 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter and nine months ended September 30, 2013, were $71.7 million and $185.4 million, respectively, as compared to $50.1 million and $150.6 million, respectively, for the same periods in 2012.

Selling, general and administrative expenses for the quarter and nine months ended September 30, 2013, were $26.4 million and $72.0 million, respectively, as compared to $20.5 million and $61.6 million, respectively, for the same periods in 2012.

Interest Expense and 4.75% Convertible Senior Notes

Interest expense for the quarter and nine months ended September 30, 2013, was $7.7 million and $29.7 million, respectively, as compared to $11.6 million and $34.3 million, respectively, for the comparable periods in 2012. Included in interest expense for the quarter and nine months ended September 30, 2013, were $4.7 million and $17.9 million, respectively, of non-cash charges to amortize the discount on the 4.75% Senior Notes, as compared to $6.8 million and $20.0 million, respectively, for the same periods in 2012.

During the third quarter, the Company entered into separately negotiated agreements with certain holders of the Company's 4.75% Senior Notes pursuant to which such holders agreed to exchange $37.3 million in aggregate principal amount of the 4.75% Senior Notes for the shares of the Company's stock into which the 4.75% Senior Notes were convertible, aggregating 4.2 million shares, and $1.5 million in cash. The Company recorded the $1.5 million in debt exchange expense in the third quarter. For the year to date, the Company has entered into separately negotiated agreements with certain holders of the Company's 4.75% Senior Notes pursuant to which such holders agreed to exchange a total of $181.0 million in aggregate principal amount of the 4.75% Senior Notes for the shares of the Company's stock into which the 4.75% Senior Notes were convertible, aggregating 20.6 million shares, and $11.3 million in cash. The Company has recorded $11.3 million in debt exchange expense year to date.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

RESPONSE, a Phase III study being conducted under a Special Protocol Assessment (SPA) in collaboration with Novartis, is evaluating ruxolitinib in patients with polycythemia vera (PV), and results are expected in early 2014. Completion of this pivotal trial, if positive, would allow for the filing of a supplemental new drug application in the first half of 2014.

RELIEF is an ongoing Phase III trial measuring disease-related symptoms in patients with PV. Once completed, the trial results, if positive, are expected to be submitted to support labeling claims regarding the symptomatic benefit of ruxolitinib in PV. Data are expected in mid-2014.

An overall survival analysis of top-line results of the Phase II proof-of-concept trial (RECAP) of ruxolitinib in combination with capecitabine in patients with refractory metastatic pancreatic cancer demonstrated a hazard ratio of 0.79 and a pre-specified subgroup analysis achieved a significant benefit with a hazard ratio of 0.47. The results of the randomized, double-blind, placebo-controlled trial are expected to be used to support a pivotal registration program in metastatic pancreatic cancer as well as several Phase II trials in other solid tumors. Full results of the RECAP trial are expected to be presented at a future scientific meeting.

A Phase I trial to evaluate the safety and tolerability of ruxolitinib in combination with gemcitabine with or without nab-paclitaxel in patients with advanced solid tumors is ongoing.

Multiple investigator-sponsored trials are ongoing to evaluate ruxolitinib in oncologic indications, including advanced hematologic malignancies, relapsed or refractory acute leukemia, lymphoma and breast cancer.

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 Eli Lilly and Company, is ongoing.

A Phase II trial in patients with moderate-to-severe psoriasis is also ongoing, with results anticipated in 2014. The results from an ongoing Phase II trial in patients with diabetic nephropathy are expected in 2015.

INCB39110 – a JAK1 Inhibitor

Results of a 28-day, double-blind, placebo-controlled, dose-escalation Phase II proof-of-concept clinical trial evaluating INCB39110 in 50 patients with chronic plaque psoriasis were presented at the 2013 European Academy of Dermatology and Venereology Congress in October. In the trial, evidence of efficacy was observed in patients treated with INCB39110 at all doses as measured by static physician global assessment (sPGA) and psoriasis area and severity index (PASI) as compared to patients treated with placebo. INCB39110 was generally well-tolerated.

Results of a 12-week, placebo-controlled, dose-escalation Phase II proof-of-concept clinical trial evaluating INCB39110 in 60 patients with active rheumatoid arthritis were presented at the 2013 American College of Rheumatology / Association of Rheumatology Health Professionals Annual Scientific Meeting in October. In the trial, treatment with INCB39110 showed efficacy at all doses as measured by ACR 20, ACR 50, ACR 70 and DAS 28 scores as compared to placebo, and the compound was generally well-tolerated.

Data from the Phase II proof-of-concept trial evaluating INCB39110 in patients with myelofibrosis are expected to be presented at the 2013 American Society of Hematology annual meeting in December.

A Phase I clinical trial to evaluate the safety and tolerability of INCB39110 in combination with gemcitabine and nab-paclitaxel in patients with advanced solid tumors was initiated in July.

INCB47986 – a JAK1 Inhibitor

A second JAK1 inhibitor, INCB47986, is currently being evaluated in a Phase I clinical trial in patients with advanced malignancies.

INCB24360 – an IDO1 Inhibitor

INCB24360 is currently being evaluated in a Phase I/II trial in combination with ipilimumab for metastatic melanoma and in a Phase II trial as

monotherapy for ovarian cancer.

An investigator-sponsored trial is underway to evaluate INCB24360 in patients with myelodysplastic syndrome (MDS), and a cooperative group study is underway to evaluate the IDO1 inhibitor in combination with vaccine therapy in patients with melanoma.

INCB40093 – a PI3K-delta Inhibitor

INCB40093 has completed single- and multi-dose Phase I studies in healthy volunteers and is currently in a Phase I dose-escalation trial in patients with B-lymphoid malignancies.

INC280 – a c-MET Inhibitor

Under the Incyte-Novartis Collaboration and License Agreement, further development of this compound is being conducted by Novartis. INC280 is being evaluated as monotherapy in advanced c-MET positive hepatocellular carcinoma and c-MET dependent advanced solid malignancies as well as combination therapy with gefitinib in c-MET positive/EGFR-TKI-resistant non-small-cell lung cancer.

Conference Call Information

Incyte will hold its third-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, 421882.

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, 421882.

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.

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. Do not drink grapefruit juice while taking 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.jakafi.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 the Company's plans and expectations with respect to Jakafi ® (ruxolitinib), including its potential efficacy and therapeutic and commercial value, its potential approval in polycythemia vera in late 2014 and potential benefit in pancreatic cancer and opportunities in other solid tumors; the Company's 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; the Company's expectation of results from the RELIEF trial in mid-2014 and the submission of those results to support labeling claims on symptomatic benefit of ruxolitinib in PV; the Company's expectation of using the results from the RECAP trial to support a pivotal registration program in metastatic pancreatic cancer as well as several Phase II trials in other solid tumors and to present the results at a future scientific meeting; the Company's expectation of results from the trials evaluating baricitinib in patients with moderate-to-severe psoriasis and diabetic nephropathy in 2014 and 2015, respectively; and the Company's expectation to present results from the proof-of-concept trial evaluating INCB39110 in patients with myelofibrosis at the 2013 ASH annual meeting, 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, 2013.

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 September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Product revenues, net	$ 60,201	$ 43,695	$162,589	$ 92,700
Product royalty revenues	8,184	-	19,893	-
Contract revenues	16,737	16,737	75,211	90,211
Other revenues	1	60	182	302
Total revenues	85,123	60,492	257,875	183,213
Costs and expenses:				
Cost of product revenues	155	31	463	58
Research and development	71,704	50,079	185,417	150,627
Selling, general and administrative	26,447	20,520	71,956	61,634
Total costs and expenses	98,306	70,630	257,836	212,319
Income (loss) from operations	(13,183)	(10,138)	39	(29,106)
Interest and other income, net	385	27	829	393
Interest expense	(7,699)	(11,573)	(29,720)	(34,293)
Debt exchange expense	(1,491)	-	(11,262)	-
Loss before income taxes	(21,988)	(21,684)	(40,114)	(63,006)
Provision for income taxes	49	26	162	93
Net loss	$(22,037)	$(21,710)	$(40,276)	$(63,099)
Basic and diluted net loss per share	$ (0.14)	$ (0.17)	$ (0.28)	$ (0.49)
Shares used in computing basic and diluted net loss per share	155,067	130,851	143,899	129,093

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, 2013	December 31, 2012
Cash, cash equivalents, and short-term marketable securities	291,174	228,418
Accounts receivable, net	33,197	70,951
Total assets	357,400	330,419
Convertible senior notes(1)	187,136	322,043
Convertible subordinated notes	-	9,033
Total stockholders' equity (deficit)	28,791	(174,957)

(1) Net of unamortized debt discount of $31.9 million and $78.0 million at September 30, 2013 and December 31, 2012, respectively.

Source: Incyte Corporation

Incyte Corporation
Pamela M. Murphy
Vice President, Investor Relations & Corporate Communications
302-498-6944