Incyte Reports 2012 Fourth-Quarter and Full-Year Financial Results; Provides 2013 Financial Guidance; Updates Shareholders on Key Clinical Programs

February 14, 2013

- *$43.3 million of fourth-quarter and $136.0 million of full-year 2012 net product revenues from Jakafi® (ruxolitinib)*
- *Net product revenue guidance for 2013 in the range of $210 million to $225 million*
- *$50 million milestone earned from Eli Lilly for initiation of Phase III clinical program for baricitinib in rheumatoid arthritis*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 14, 2013-- Incyte Corporation (Nasdaq: INCY) today reported fourth-quarter and full-year 2012 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 provided 2013 financial guidance and updated information about key clinical programs, including key Phase III data for Jakafi that was presented at the 2012 American Society of Hematology (ASH) Annual Meeting.

"The recent data from ASH highlighting long-term results from COMFORT-I and II show that continued use of Jakafi by appropriate patients with myelofibrosis not only provides durable benefits for spleen reduction and symptom improvement, but also improved survival, suggesting an overall survival benefit," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer. "I believe these data, over time, will lead to earlier use in the course of this progressive disease."

"We are very pleased with our quarter over quarter growth in underlying demand, which was 17 percent," stated Jim Daly, Incyte's Executive Vice President and Chief Commercial Officer. "Given the solid foundation we've established for Jakafi, I'm confident that we'll continue to see consistent growth over the next several years and have set net product revenue guidance for 2013 in the range of $210 million to $225 million."

2012 Fourth-Quarter and Full-Year Financial Results

Cash Position

As of December 31, 2012, cash, cash equivalents and marketable securities totaled $228.4 million compared to $277.6 million as of December 31, 2011. The December 31, 2012, amount does not include the $50.0 million milestone payment from Lilly for the advancement of baricitinib into Phase III clinical trials, which was earned in the fourth-quarter of 2012 and received in January 2013.

Product Revenues and Royalties

For the quarter and full year ended December 31, 2012, net product revenues of Jakafi were $43.3 million and $136.0 million, respectively. For the same periods in 2011, net product revenues were $2.0 million, which represents product revenues from the launch of Jakafi on November 22, 2011, to December 31, 2011. Product royalties from sales of Jakavi® outside the United States by our collaboration partner Novartis for the quarter and full year ended December 31, 2012, were $3.7 million; there were no product royalties earned in 2011.

Total Revenues

Total revenues for the quarter ended December 31, 2012, were $113.8 million as compared to $28.9 million for the same period in 2011. Total revenues for the full year ended December 31, 2012, were $297.1 million as compared to $94.5 million for the same period in 2011. The increase in total revenue from 2011 to 2012 was primarily related to a full year of Jakafi product revenue, $90.0 million in milestone payments earned under our collaborations with Eli Lilly and Novartis, and $3.7 million of Jakavi product royalties from Novartis. Total revenues for the full year ended December 31, 2011, included $25.0 million in milestone payments received under our collaboration with Novartis.

Net Income/Loss

Quarter Ended December 31, 2012

Net income for the quarter ended December 31, 2012, was $18.8 million, or $0.14 per basic and diluted share, as compared to a net loss of $55.1 million, or $0.44 per basic and diluted share, for the same period in 2011. The change from a net loss in the fourth quarter of 2011 to net income in the fourth quarter of 2012 is primarily due to a full quarter of Jakafi product revenues and a $50.0 million milestone payment earned under our collaboration with Lilly related to baricitinib.

Year Ended December 31, 2012

Net loss for the full year 2012 was $44.3 million, or $0.34 per basic and diluted share as compared to a net loss of $186.5 million, or $1.49 per basic and diluted share, for the full year 2011. The decrease in net loss from 2011 to 2012 is primarily due to a full year of Jakafi product revenue and $90.0 million in milestone payments earned under our collaborations with Lilly and Novartis.

Non-Cash Stock Option Expense

Included in net income for the quarter ended December 31, 2012, was $9.1 million of non-cash expense related to employee stock options, of which

$6.0 million was included in research and development expenses and $3.1 million was included in selling, general and administrative expenses. Included in net loss for the quarter ended December 31, 2011, was $7.4 million of non-cash expense related to employee stock options, of which $4.6 million was included in research and development expenses and $2.8 million was included in selling, general and administrative expenses.

Included in net loss for the year ended December 31, 2012, was $38.5 million of non-cash expense related to employee stock options, of which $25.5 million was included in research and development expenses and $13.0 million was included in selling, general and administrative expenses. Included in net loss for the year ended December 31, 2011, was $29.0 million of non-cash expense related to employee stock options, of which $18.6 million was included in research and development expenses and $10.4 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter ended December 31, 2012, were $59.8 million, as compared to $51.9 million for the same period in 2011. Research and development expenses for the full year 2012 were $210.4 million, as compared to $178.7 million for 2011.

The increase in research and development expenses for the quarter and full year ended December 31, 2012, compared to the comparable prior year periods was due to the advancement of the Company's pipeline and increased non-cash employee stock option expense. 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 December 31, 2012, were $23.7 million, as compared to $21.2 million for the same period in 2011. Selling, general and administrative expenses for the full year 2012 were $85.4 million, as compared to $58.2 million for 2011.

Increased selling, general and administrative expenses for the quarter and full year ended December 31, 2012, compared to the comparable prior year periods reflected the additional costs related to the commercialization of Jakafi.

Interest Expense

Interest expense for the quarter and full year ended December 31, 2012, was $11.8 million and $46.1 million, respectively, as compared to $11.2 million and $43.8 million for the comparable periods in 2011. Included in interest expense for the quarter and the year ended December 31, 2012, was $7.0 million and $27.1 million, respectively, of non-cash charges to amortize the discount on the Company's 4.75% Convertible Senior Notes due 2015, as compared to $6.4 million and $24.8 million for the same periods in 2011. Increased interest expense for the full year 2012 is primarily attributable to the accretion of the discount related to the 4.75% Convertible Senior Notes.

2013 Financial Guidance

- Product Revenues: The Company expects that Jakafi net product revenues will be in the range of $210 million to $225 million. This range excludes any product royalty revenues received from Novartis on sales of Jakavi.
- Contract Revenues: The Company expects to receive a $60 million milestone payment under its collaboration with Novartis when European Union pricing approval for Jakavi in specific countries is received. Excluding any other potential milestones received under collaborations, the Company expects revenues of $66 million from the amortization of the upfront payments received under the Novartis and Lilly collaborative agreements.
- Research and Development Expenses: The Company expects that research and development expenses will be in the range of $260 million to $270 million, including a non-cash expense of approximately $25 million to $28 million related to the impact of expensing employee stock options. The increase in research and development expense is primarily the result of co-development of baricitinib in Phase III studies in rheumatoid arthritis with Lilly and broad investment expected in our clinical pipeline to support multiple ongoing research and development activities.
- Selling, General and Administrative Expenses: The Company expects selling, general and administrative expenses to be in the range of $100 million to $110 million, including a non-cash expense of approximately $14 million to $17 million related to the impact of expensing employee stock options. The increase in selling, general and administrative expenses is primarily the result of additional programs to support the ongoing commercialization of Jakafi.
- Interest Expense: The Company expects interest expense to be approximately $47 million, including a non-cash expense of $28 million related primarily to the amortization of the discount on the 4.75% Convertible Senior Notes.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

The use of Jakafi to treat patients with intermediate or high-risk myelofibrosis (MF) is further supported by presentations made at the American Society of Hematology annual meeting in December 2012, including updates from COMFORT-I and COMFORT-II. The long-term results from COMFORT-I, which compared Jakafi to placebo, showed that continued use of Jakafi provided durable reductions in spleen volume, durable improvements in quality of life measures and improved survival, suggesting an overall survival advantage. The COMFORT-II two-year follow-up showed a similar increase in survival for patients initially randomized to Jakafi compared to those randomized to best available therapy.

Data presented at ASH included results from a three-year follow-up of patients with polycythemia vera (PV) in a Phase II study, showing that ruxolitinib treatment resulted in durable overall response rates by modified European Leukemia Net criteria and improvements in PV-related symptoms.

Two Phase III clinical trials (RESPONSE and RELIEF), in partnership with Novartis, are underway to evaluate ruxolitinib in patients with

PV, and results are expected to be part of a supplemental new drug application submission in 2014. The FDA has granted fast track designation for PV, specifically for the treatment of patients with PV who are resistant to or intolerant of hydroxyurea. Recruitment of the RESPONSE study has been completed.

A randomized Phase II trial of ruxolitinib in combination with capecitabine is fully enrolled with approximately 135 patients with recurrent or treatment refractory metastatic pancreatic cancer (the RECAP trial), with final results expected in the second half of 2013.

Multiple investigator-sponsored trials evaluating ruxolitinib are ongoing, including two Phase I/II trials in adults with advanced hematologic malignancies (acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome and chronic myelogenous leukemia) and relapsed or refractory acute leukemia; a Phase I/II trial in children with hematologic malignancies and solid tumors; and a Phase II trial in patients with lymphoma. In addition, two of several planned investigator-sponsored Phase II trials to evaluate ruxolitinib in treating patients with breast cancer have been initiated.

Baricitinib - a JAK1 and JAK2 Inhibitor

Data from the six-month Phase IIb trial of baricitinib in patients with rheumatoid arthritis, conducted by our collaboration partner Eli Lilly, were presented at the American College of Rheumatology Annual Scientific Meeting in November 2012. Positive results from the 12- to 24-week portion of the study, which did not include continuation of the placebo control past week 12, showed that patients who received 2 mg, 4 mg or 8 mg baricitinib once-daily doses maintained or improved ACR20, ACR50 and ACR70 responses.

The Phase III program to evaluate baricitinib in patients with rheumatoid arthritis, conducted by Lilly, started randomized treatments in November 2012.

A Phase IIb trial in patients with moderate to severe psoriasis, conducted by Lilly, is ongoing with primary endpoint results expected in 2013.

A Phase II trial in patients with diabetic nephropathy, conducted by Lilly, was initiated in August 2012, and results are expected in 2014.

INCB28060 (also known as INC280) – a c-MET Inhibitor

The initial Phase I trial in patients with solid tumors has been completed. This compound is licensed to Novartis as part of the Incyte-Novartis collaboration, and further development will be conducted by Novartis.

INCB24360 – an Indoleamine Dioxygenase-1 (IDO1) Inhibitor

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

Early-Stage Development and Discovery Programs

Several early development and discovery programs in oncology and inflammation are also ongoing.

Conference Call Information

Incyte will hold its fourth-quarter 2012 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, 407848.

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, 407848.

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 $<200 \times 10^9$/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 financial guidance about expected net product revenues, contract revenues, research and development expenses, selling, general and administrative expenses and interest expense, expectations regarding 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 regarding continued consistent growth, our expectation that results from the RESPONSE and RELIEF trials are expected to be part of a sNDA submission in 2014, our expectation of final results from the RECAP trial in the second half of 2013, and our expectation that results from the trials conducted by our collaboration partner Eli Lilly evaluating baricitinib in patients with moderate to severe psoriasis and diabetic nephropathy will be available in 2013 and 2014, respectively, 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-Q for the quarter ended September 30, 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 December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Product revenues, net	$ 43,301	$ 2,012	$136,001	$ 2,012
Product royalty revenues	3,652	—	3,652	—
Contract revenues	66,737	26,737	156,948	91,948
Other revenues	155	140	458	495
Total revenues	113,845	28,889	297,059	94,455
Costs and expenses:				
Cost of product revenues	99	—	157	—
Research and development	59,763	51,877	210,391	178,707
Selling, general and administrative	23,729	21,152	85,363	58,219
Other expenses	—	—	—	712
Total costs and expenses	83,591	73,029	295,911	237,638

Income (loss) from operations	30,254	(44,140)	1,148	(143,183)
Interest and other income, net	371	213	764	462
Interest expense	(11,765)	(11,153)	(46,058)	(43,819)
Income (loss) before income taxes	18,860	(55,080)	(44,146)	(186,540)
Provision for income taxes	81	—	174	—
Net income (loss)	$ 18,779	$(55,080)	$(44,320)	$(186,540)
Net income (loss) per share				
Basic	$ 0.14	$ (0.44)	$ (0.34)	$ (1.49)
Diluted	$ 0.14	$ (0.44)	$ (0.34)	$ (1.49)
Shares used in computing basic and diluted net income (loss) per share				
Basic	131,711	126,388	129,747	125,362
Diluted	139,118	126,388	129,747	125,362

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	December 31, 2012	December 31, 2011
Cash, cash equivalents, and short-term marketable securities	$ 228,418	$ 277,594
Accounts receivable, net	70,951	6,415
Total assets	330,419	328,962
Convertible senior notes(1)	322,043	298,193
Convertible subordinated notes	9,033	17,960
Total stockholders' deficit	(174,957)	(227,077)

(1) Net of unamortized debt discount of $78.0 million and $101.8 million at December 31, 2012, and December 31, 2011, respectively.

Source: Incyte Corporation

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