Incyte Reports 2013 Fourth-Quarter and Year-End Financial Results; Provides 2014 Financial Guidance; Updates Shareholders on Key Clinical Programs

February 12, 2014

- *$72.9 million of fourth-quarter and $235.4 million of full-year 2013 net product revenues from Jakafi® (ruxolitinib)*
- *Net product revenue guidance for 2014 in the range of $315 million to $335 million, reflecting continued growth in underlying demand*
- *Special Protocol Assessment obtained for Phase III clinical trial of ruxolitinib in advanced or metastatic pancreatic cancer*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 12, 2014-- Incyte Corporation (Nasdaq: INCY) today reported 2013 fourth-quarter and year-end 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 2014 financial guidance and highlighted multiple achievements in its clinical programs, including agreement with the FDA for a Special Protocol Assessment (SPA) for a registration trial of ruxolitinib in patients with advanced or metastatic pancreatic cancer.

"I have great confidence that Incyte is well-positioned to continue to grow as a successful biopharmaceutical company focused on oncology," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "Jakafi continues to perform well in myelofibrosis, and we believe it will offer substantial growth in a second blood cancer, polycythemia vera. Additionally, we're encouraged by data from the RECAP Phase II trial suggesting that JAK inhibition may extend and improve patient outcomes in pancreatic cancer and possibly in other solid tumors."

"Beyond our JAK programs, we have a clinical pipeline that includes oral inhibitors of IDO1 and PI3K-delta, and the recent announcement regarding our clinical trial collaboration with Merck is an important step to furthering our understanding of the role of our oral IDO1 inhibitor in the rapidly evolving field of immunotherapy."

2013 Fourth-Quarter and Full-Year Financial Results

Net Loss/Income

Quarter Ended December 31, 2013

Net loss for the quarter ended December 31, 2013, was $42.9 million, or $0.26 per basic and diluted share, as compared to net income of $18.8 million, or $0.14 per basic and diluted share, for the same period in 2012. Included in the net loss for the quarter ended December 31, 2013, was a one-time charge of $17.9 million, or $0.11 per basic and diluted share, related to the repurchase of $117.3 million face amount of the Company's 4.75% Convertible Senior Notes due 2015 (2015 Notes) as described below. Excluding this one-time charge, the net loss for the quarter was $0.15 per basic and diluted share. The table at the end of this press release includes a reconciliation of GAAP to Non-GAAP basic and diluted net loss per share.

Year Ended December 31, 2013

Net loss for the full year ended December 31, 2013 was $83.1 million, or $0.56 per basic and diluted share, as compared to a net loss of $44.3 million, or $0.34 per basic and diluted share, for the same period in 2012. The increase in net loss from 2012 to 2013 is primarily due to $11.5 million in debt exchange expense for senior note conversions related to separately negotiated agreements with certain holders of the 2015 Notes, and a $17.9 million one-time charge, or $0.12 per basic and diluted share, related to the repurchase of $117.3 million face amount of the 2015 Notes as described below. Excluding this one-time charge, the net loss for the year was $0.44 per basic and diluted share. The table at the end of this press release includes a reconciliation of GAAP to Non-GAAP basic and diluted net loss per share.

Revenues

For the quarter and full year ended December 31, 2013, net product revenues of Jakafi were $72.9 million and $235.4 million, respectively, as compared to $43.3 million and $136.0 million, respectively, for the same periods in 2012.

For the quarter and full year ended December 31, 2013, product royalties from sales of Jakavi® (ruxolitinib) outside the United States received from the Company's collaboration partner Novartis were $8.4 million and $28.3 million, respectively as compared to $3.7 million for each of the same periods in 2012.

For the quarter and full year ended December 31, 2013, contract revenues were $15.8 million and $91.0 million, respectively, as compared to $66.7 million and $156.9 million, respectively, for the same periods in 2012. The decrease in 2013 contract revenues relates to the achievement of milestones in 2012 as compared to 2013. During the year ended December 31, 2013, contract revenues included a $25.0 million milestone payment received from Novartis related to our c-Met program. During the year ended December 31, 2012, contract revenues included a $40.0 millionEuropean Union regulatory milestone payment received from Novartis related to Jakavi, as well as a $50.0 million milestone payment received from Eli Lilly and Company related to baricitinib.

For the quarter and full year ended December 31, 2013, total revenues were $97.1 million and $354.9 million, respectively, as compared to $113.8 million and $297.1 million, respectively, for the same periods in 2012.

Non-Cash Stock Option Expense

Included in net loss for the quarter ended December 31, 2013, was $9.8 million of non-cash expense related to employee stock options, of which $6.7 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 full year ended December 31, 2013, was $38.4 million of non-cash expense related to employee stock options, of which $26.2 million was included in research and development expenses and $12.2 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter and full year ended December 31, 2013, were $75.0 million and $260.4 million, respectively, as compared to $59.8 million and $210.4 million, respectively, for the same periods in 2012.

The increase in research and development expenses for the quarter and full year ended December 31, 2013, compared to the comparable prior year periods, was due to the expansion of the Company's pipeline.

Selling, general and administrative expenses for the quarter and full year ended December 31, 2013, were $38.0 million and $110.0 million, respectively, as compared to $23.7 million and $85.4 million, respectively, for the same periods in 2012.

Increased selling, general and administrative expenses for the quarter and full year ended December 31, 2013, compared to the comparable prior year periods reflected the additional costs related to the commercialization of Jakafi in MF and preparation for the anticipated launch in polycythemia vera.

Interest and Other Expenses Related to Convertible Senior Notes

During the fourth quarter of 2013, the Company completed a private placement of $750.0 million aggregate principal amount of convertible senior notes. The Company issued $375.0 million aggregate principal amount of 0.375% Convertible Senior Notes due 2018 (2018 Notes) and $375.0 million aggregate principal amount of 1.25% Convertible Senior Notes due 2020 (2020 Notes). The Company used a portion of the net proceeds from this offering to repurchase a total of $117.3 million aggregate principal amount of the outstanding 2015 Notes for an aggregate consideration, including accrued interest, of approximately $500.0 million. The repurchase resulted in a one-time charge of $17.9 million during the fourth quarter. The private placement offering of the 2018 and 2020 Notes, less the cash paid for the repurchase of $117.3 million of 2015 Notes and offering costs, resulted in net cash proceeds of approximately $229.0 million.

During the year, the Company entered into separately negotiated agreements with certain holders of the 2015 Notes pursuant to which such holders agreed to exchange $186.0 million aggregate principal amount of the 2015 Notes for the shares of the Company's stock into which the 2015 Notes were convertible, aggregating 21.2 million shares, and $11.5 million in cash. The Company recorded $11.5 million in debt exchange expense on senior note conversions for the year ended December 31, 2013.

Interest expense for the quarter and full year ended December 31, 2013, was $8.9 million and $38.7 million, respectively, as compared to $11.8 million and $46.1 million for the same periods in 2012. Included in interest expense for the quarter and the year ended December 31, 2013, was $6.3 million and $23.8 million, respectively, of non-cash charges to amortize the discount on the Company's 2015 Notes, 2018 Notes and 2020 Notes, as compared to $7.0 million and $27.1 million to amortize the discount on the Company's 2015 Notes for the same periods in 2012.

Cash and Marketable Securities Position

As of December 31, 2013, cash, cash equivalents and marketable securities totaled $509.0 million compared to $228.4 million as of December 31, 2012.

2014 Financial Guidance

Product Revenues: The Company expects that Jakafi net product revenues will be in the range of $315 million to $335 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 agreement with Novartis when European Union pricing approval for Jakavi is received in a third major European country. Excluding any other potential milestones received under collaborations, the Company expects revenues of approximately $13 million from the amortization of the upfront payments received under its collaboration agreement with Lilly.

Research and Development Expenses: The Company expects that research and development expenses will be in the range of $350 million to $370 million, including a non-cash expense of approximately $30 million to $35 million related to the impact of expensing employee stock options. The increase in research and development is primarily related to our broad investment in the clinical pipeline, including the advancement of ruxolitinib and our JAK1 inhibitor, INCB39110, in solid tumors and the development of our IDO1 inhibitor, INCB24360, in multiple oncologic indications in combination with checkpoint inhibitors.

Selling, General and Administrative Expenses: The Company expects selling, general and administrative expenses to be in the range of $145 million to $155 million, including a non-cash expense of approximately $28 million to $30 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 in MF and preparation for the anticipated launch in polycythemia vera.

Interest Expense: The Company expects interest expense to be approximately $48 million, including a non-cash expense of $37 million related to the amortization of the discount on the 2015 Notes, 2018 Notes and 2020 Notes.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

Myeloproliferative Neoplasms

Data from multiple presentations at the 2013 American Society of Hematology (ASH) annual meeting, including a three-year follow-up analysis from COMFORT-I and a pooled analysis of the two COMFORT trials, suggest that patients with myelofibrosis who are treated with Jakafi maintained reductions in spleen volume and had improved survival over placebo and best available therapy. A separate retrospective analysis, comparing patients from COMFORT-II and patients in the Dynamic International Prognostic Scoring System database, suggests that Jakafi treatment may reduce the risk of death by approximately 50 percent compared to conventional treatments. Additionally, in an exploratory analysis of data collected over five years in the ongoing Phase II trial, a higher percentage of ruxolitinib-treated patients with myelofibrosis showed stabilization or improvement of bone marrow fibrosis as compared to a separate historical control cohort of patients treated with best available therapy.

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) who are resistant to or intolerant of hydroxyurea. 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 fully enrolled Phase III trial measuring disease-related symptoms in patients with PV. Data are expected in mid-2014.

Solid Tumors

The FDA has granted orphan status for ruxolitinib for the treatment of pancreatic cancer, and the Company and FDA have agreed on an SPA for a registration trial for advanced or metastatic pancreatic cancer. Under the SPA, the Phase III study can be limited to the subgroup that showed positive results identified in the Phase II clinical trial (RECAP) and there is no requirement to develop a companion diagnostic. While one trial with sufficiently robust results may be sufficient to support approval, a second nearly identical Phase III trial is planned. Both double-blinded, placebo-controlled trials are expected to begin in the first half of 2014.

Three additional blinded Phase II proof-of-concept trials focusing on survival in non-small cell lung cancer, breast cancer and colon cancer studying patients in the subgroup identified in RECAP are also expected to initiate in the first half of 2014.

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.

Phase II trials in patients with moderate-to-severe psoriasis and patients with diabetic nephropathy are also ongoing, with results anticipated in 2014 and 2015, respectively.

INCB39110 – a JAK1 Inhibitor

The clinical program to evaluate INCB39110 in solid tumors is planned to start with two blinded Phase II trials of INCB39110 in non-small cell lung cancer that are expected to initiate in the first half of 2014. The primary endpoint of both studies will be overall survival.

INCB47986 – a JAK1 Inhibitor

A Phase I clinical trial of a second JAK1 inhibitor, INCB47986, in healthy volunteers has been completed, and a Phase II trial of the compound in patients with rheumatoid arthritis is planned for the first half of 2014.

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. Based on preclinical data that suggest synergy in combining an IDO1 inhibitor with checkpoint inhibitors for improved anti-tumor response, the Company has established a clinical trial collaboration to evaluate the combination of INCB24360 and Merck's investigational anti-PD-1 immunotherapy, MK-3475, in a Phase I/II study in previously treated metastatic and recurrent non-small cell lung cancer and other advanced or metastatic cancers. The study is expected to initiate in the first half of 2014. The Company is also working to establish additional clinical collaborations with other companies, cancer networks and academia.

INCB40093 – a PI3K-delta Inhibitor

INCB40093 is currently in a Phase I dose-escalation trial in patients with B-lymphoid malignancies. A Phase I study in combination with the Company's JAK1 inhibitor, INCB39110, in the same patient group was initiated in January 2014.

INC280 – a c-MET Inhibitor

Under the Incyte-Novartis collaboration and license agreement, Novartis is evaluating INC280 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 2013 fourth-quarter and year-end 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, 13574983.

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, 13574983.

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 financial guidance about expected net product revenues, contract revenues, cost of product revenues, research and development expenses, selling, general and administrative expenses and interest expense; the Company's plans and expectations for the future, including the potential for substantial growth for Jakafi® (ruxolitinib) in polycythemia vera, and the possibility that JAK inhibition may extend and improve patient outcomes in pancreatic cancer and other solid tumors; the Company's plans and expectations with respect to Jakafi, including its potential efficacy and therapeutic and commercial value, its potential to improve survival and bone marrow fibrosis, and its potential in other oncologic indications; the Company's expectation to file a supplemental new drug application for ruxolitinib for polycythemia vera in the first half of 2014; the Company's expectation of results from the RELIEF trial in mid-2014; regarding ruxolitinib in advanced or metastatic pancreatic cancer, the possibility that one trial with sufficiently robust results may be sufficient to support approval and that two Phase III trials are planned and expected to begin in the first half of 2014; the Company's expectation to initiate three additional Phase II proof-of-concept trials evaluating ruxolitinib in non-small cell lung cancer, breast cancer and colon cancer in patients in the subgroup identified in RECAP in the first half of 2014; the Company's expectation of results from the trials conducted by its collaboration partner Lilly evaluating baricitinib in patients with moderate-to-severe psoriasis and diabetic nephropathy in 2014 and 2015, respectively; the Company's plans for INCB39110 in oncologic indications, including initiating two Phase II trials in patients with non-small cell lung cancer in the first half of 2014; the Company's plans for a Phase II trial of INCB47986 in patients with rheumatoid arthritis for the first of 2014; the Company's expectation to initiate a Phase I/II study evaluating the combination of INCB24360 and MK-3475 in the first half of 2014; and the Company's plans to establish additional clinical collaborations for its IDO1 inhibitor 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 September 30, 2013.

INCYTE CORPORATION
Reconciliation of Non-GAAP Measures
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31, 2013	Twelve Months Ended December 31, 2013
Net loss - as reported	$ (42,870)	$ (83,147)
Loss on repurchase of convertible senior notes	17,934	17,934
Net loss - as adjusted	$ (24,936)	$ (65,213)

Basic and diluted net loss per share - as reported	$	(0.26)	$	(0.56)
Loss on repurchase of convertible senior notes		0.11		0.12
Basic and diluted net loss per share - as adjusted	$	(0.15)	$	(0.44)

Net loss - as adjusted, and basic and diluted net loss per share - as adjusted (excluding a one-time charge related to the difference between the face amount and carrying value related to the repurchase of 2015 Notes) is a non-GAAP financial measure and should not be considered a replacement for GAAP results. A reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure is presented above. The Company believes that presentation of this non-GAAP financial measure provides useful supplementary information to, and facilitates additional analysis by, investors by showing the effect of the one-time repurchase of a portion of the outstanding 2015 Notes on our net loss for the three months and twelve months ended December 31, 2013.

INCYTE CORPORATION

Condensed Consolidated Statements of Operations

(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Revenues:				
Product revenues, net	$ 72,854	$ 43,301	$ 235,443	$ 136,001
Product royalty revenues	8,358	3,652	28,251	3,652
Contract revenues	15,836	66,737	91,047	156,948
Other revenues	24	155	206	458
Total revenues	97,072	113,845	354,947	297,059
Costs and expenses:				
Cost of product revenues	167	99	630	157
Research and development	75,020	59,763	260,436	210,391
Selling, general and administrative	38,028	23,729	109,983	85,363
Total costs and expenses	113,215	83,591	371,049	295,911
Income (loss) from operations	(16,143)	30,254	(16,102)	1,148
Interest and other income, net	497	371	1,324	764
Interest expense	(8,932)	(11,765)	(38,652)	(46,058)
Debt exchange expense on senior note conversions	(221)	-	(11,484)	-
Loss on repurchase of senior notes	(17,934)	-	(17,934)	-
Income (loss) before income taxes	(42,733)	18,860	(82,848)	(44,146)
Provision for income taxes	137	81	299	174
Net income (loss)	$(42,870)	$ 18,779	$ (83,147))	$ (44,320)
Net income (loss) per share				
Basic	$ (0.26)	$ 0.14	$ (0.56)	$ (0.34)
Diluted	$ (0.26)	$ 0.14	$ (0.56)	$ (0.34)
Shares used in computing basic and diluted net income (loss) per share				
Basic	161,914	131,711	148,403	129,747
Diluted	161,914	139,118	148,403	129,747

INCYTE CORPORATION

Condensed Consolidated Balance Sheet Data

(unaudited, in thousands)

	December 31, 2013	December 31, 2012
Cash, cash equivalents, and short-term marketable securities	$ 509,004	$ 228,418
Accounts receivable, net	35,374	70,951
Total assets	629,568	330,419
Convertible senior notes(1)	661,567	322,043
Convertible subordinated notes	-	9,033
Total stockholders' deficit	(193,108)	(174,957)

(1) Net of unamortized debt discount of $185.0 million and $78.0 million at December 31, 2013, and December 31, 2012, respectively.

Source: Incyte Corporation

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