Incyte Reports 2014 Fourth-Quarter and Year-End Financial Results; Provides 2015 Financial Guidance; Updates Shareholders on Key Clinical Programs

February 12, 2015

- *$106 million of 2014 fourth-quarter net product revenues from Jakafi® (ruxolitinib), representing 46 percent growth over the same period last year*
- *$358 million of 2014 full-year net product revenues from Jakafi, representing 52 percent growth over last year*
- *2015 guidance for Jakafi net product revenues in the range of $525 million to $565 million, reflecting continued growth in underlying demand in myelofibrosis (MF) and including revenue from the launch in polycythemia vera (PV)*
- *Recruitment continuing across clinical development portfolio in multiple pivotal and proof-of-concept trials*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 12, 2015-- Incyte Corporation (Nasdaq: INCY) today reported 2014 fourth-quarter and year-end financial results, including revenue from Jakafi® (ruxolitinib). The Company provided 2015 financial guidance while outlining its progress in recruiting multiple pivotal and proof-of-concept trials, including those investigating its portfolio of JAK inhibitors in a variety of cancer types, its IDO1 inhibitor in combination with other immuno-oncology agents and a series of studies investigating several other innovative targeted therapies in mono- and combination-therapy settings. The Company also highlighted the recent FDA approval of Jakafi for the treatment of patients with uncontrolled PV as well as the positive top-line results, announced with Lilly, from the first of several phase III trials of baricitinib in patients with rheumatoid arthritis.

“Our strategy is to invest in innovative science, creating new medicines which can make a positive impact on patients’ lives,” stated Hervé Hoppenot, Incyte’s President and Chief Executive Officer. “The commercial momentum at Incyte continues to provide the opportunities to drive our broad clinical development portfolio forward and the productivity and expertise of our drug discovery team continues to generate additional high-quality molecules for us to advance into clinical studies.”

Jakafi® is approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis and for the treatment of patients with PV who have had an inadequate response to or are intolerant of hydroxyurea.

2014 Fourth-Quarter and Full-Year Financial Results

Revenues

For the quarter ended December 31, 2014, net product revenues of Jakafi were $106 million as compared to $73 million for the same period in 2013, representing 46 percent growth. For the full year ended December 31, 2014, net product revenues were $358 million as compared to $235 million for the same period in 2013, representing 52 percent growth.

For the quarter and full year ended December 31, 2014, product royalties from sales of Jakavi® (ruxolitinib) outside the United States received from Novartis, the Company’s collaboration partner, were $15 million and $49 million, respectively, as compared to $8 million and $28 million, respectively, for the same periods in 2013.

For the quarter ended December 31, 2014, contract revenues, were $3 million as compared to $16 million for the same period in 2013. For the full year ended December 31, 2014, contract revenues were $105 million as compared to $91 million for the same period in 2013.

The $13 million decrease in contract revenues for the quarter ended December 31, 2014 compared to the same period in 2013 relates to the full amortization, at December 31, 2013, of the Novartis upfront payment received under the collaboration. The $14 million increase in contract revenues for the full year ended December 31, 2014 as compared to the same period in 2013 relates to an increase in milestones in 2014, partially offset by the impact of the full amortization of the Novartis upfront payment at December 31, 2013.

For the quarter ended December 31, 2014, total revenues were $124 million as compared to $97 million for the same period in 2013. For the full year ended December 31, 2014, total revenues were $511 million as compared to $355 million for the same period in 2013.

Operating Expenses

Research and development expenses for the quarter and full year ended December 31, 2014 were $99 million and $348 million, respectively, as compared to $75 million and $260 million, respectively, for the same periods in 2013.

The increase in research and development expenses for the quarter and full year ended December 31, 2014, compared to the same prior year periods, was primarily due to the expansion of the Company’s clinical portfolio, which included the costs related to the progression of ruxolitinib, our JAK1 and IDO programs in various clinical trials.

Selling, general and administrative expenses for the quarter and full year ended December 31, 2014, were $48 million and $166 million, respectively, as compared to $38 million and $110 million, respectively, for the same periods in 2013.

Increased selling, general and administrative expenses for the quarter and full year ended December 31, 2014, compared to the same prior year periods reflected the additional costs related to the commercialization of Jakafi, including the expansion of our field force, as well as the additional commercialization costs related to the launch of Jakafi in PV.

Non-Cash Stock Expense

Included in operating expenses for the quarter ended December 31, 2014 was $16 million of non-cash expense related to equity awards to our employees, of which $9 million was included in research and development expenses and $7 million was included in selling, general and administrative expenses. For the full year ended December 31, 2014, non-cash expense related to equity awards to our employees was $62 million, of which $34 million was included in research and development expenses and $28 million was included in selling, general and administrative expenses.

Interest Expense

Interest expense for the quarter and full year ended December 31, 2014, was $13 million and $47 million, respectively, as compared to $9 million and $39 million, respectively, for the same periods in 2013. Included in interest expense for the quarter and full year ended December 31, 2014, were $9 million and $36 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 (2018 Notes) and 1.25% Convertible Senior Notes due 2020 (2020 Notes), as compared to $6 million and $24 million, respectively, for the same periods in 2013.

Net Loss

Net loss for the quarter ended December 31, 2014, was $37 million, or $0.22 per basic and diluted share, as compared to a net loss of $43 million, or $0.26 per basic and diluted share, for the same period in 2013. Net loss for the full year ended December 31, 2014, was $48 million, or $0.29 per basic and diluted share, as compared to a net loss of $83 million, or $0.56 per basic and diluted share, for the same period in 2013.

Included in the net loss in 2013 was $11 million in debt exchange expense for senior note conversions related to separately negotiated agreements with certain holders of the 2015 Notes, and a $18 million one-time charge related to the repurchase of $117 million face amount of the 2015 Notes.

Cash and Marketable Securities Position

As of December 31, 2014, cash, cash equivalents and marketable securities totaled $600 million compared to $509 million as of December 31, 2013.

2015 Financial Guidance

Product Revenues: The Company expects that Jakafi net product revenues will be in the range of $525 million to $565 million. This amount excludes any product royalty revenues received from Novartis on sales of Jakavi.

Research and Development Expenses: The Company expects that research and development expenses will be in the range of $450 million to $500 million, including a non-cash expense of approximately $40 million to $45 million related to the impact of expensing employee equity awards. The expected increase in research and development is primarily related to our broad investment in the clinical portfolio, including the advancement of ruxolitinib and our lead JAK1 inhibitor, INCB39110, in solid tumors, the development of our IDO1 inhibitor, epacadostat, in multiple oncologic indications in combination with checkpoint inhibitors as well as costs related to the pending Agenus alliance.

Selling, General and Administrative Expenses: The Company expects selling, general and administrative expenses to be in the range of $180 million to $200 million, including a non-cash expense of approximately $30 million to $35 million related to the impact of expensing employee equity awards. The expected increase in selling, general and administrative expenses is primarily the result of additional programs to support the ongoing commercialization of Jakafi.

Recent Clinical Highlights

Jakafi® (ruxolitinib) – JAK1 and JAK2 Inhibitor

Myeloproliferative Neoplasms

In December 2014 the FDA approved Jakafi for the treatment of patients with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea. Jakafi, an oral medication, is the first and only product approved by the FDA for PV, a rare and progressive blood cancer.

In January 2015 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for Jakavi® (ruxolitinib) for the treatment of adult patients with PV who are resistant to or intolerant of hydroxyurea. This recommendation for approval in Europe triggered a $25 million milestone payment to the Company from Novartis, which the Company expects to record as contract revenue, and to receive, in the first quarter of 2015.

In January 2015 *The New England Journal of Medicine* (NEJM) published results from the pivotal Phase III RESPONSE clinical trial demonstrating that, compared to standard therapy, Jakafi significantly improved hematocrit control and reduced spleen volume in patients with uncontrolled PV.

Solid Tumors

The pivotal Phase III JANUS 1 and JANUS 2 studies of ruxolitinib in second line metastatic pancreatic cancer are underway, and the Company expects data from both studies in 2016. Results from three Phase II trials of ruxolitinib, being conducted in colorectal, breast and non-small cell lung cancer (NSCLC) patients, are also expected during 2016.

Each of these trials uses the same approach to patient selection, which is based on the presence of onco-inflammation as assessed by elevated systemic C-reactive protein (CRP).

INCB39110 & INCB52793 – JAK1-Selective Inhibitors

INCB39110 is in two Phase II lung cancer trials, one in combination with docetaxel and the other in combination with erlotinib, and the Company plans to begin a first line pancreatic cancer study in combination with gemcitabine and nab-paclitaxel in the second half of 2015. INCB39110 is also being studied in combination with the Company's PI3Kδ inhibitor INCB40093 in B-cell malignancies, initial results of which are expected in the first half of 2015.

INCB52793 is now in a Phase I/II dose-escalation trial in liquid tumors, and the Company has plans to initiate both mono- and combination-therapy trials, potentially in multiple myeloma.

epacadostat (INCB24360) – IDO1 Inhibitor

The trials under the four clinical trial agreements to evaluate epacadostat in combination with immune checkpoint inhibitors are now in progress. The trials are evaluating epacadostat in combination with Merck & Co's PD-1 inhibitor Keytruda ® (pembrolizumab), AstraZeneca's investigational PD-L1 inhibitor, MEDI4736, Bristol-Myers Squibb's PD-1 inhibitor, Opdivo ® (nivolumab), and Genentech's investigational PD-L1 inhibitor, MPDL3280A. Tumor types under investigation include NSCLC, melanoma, head and neck, colorectal, ovarian and pancreatic cancer, as well as lymphoma.

Immuno-Oncology Alliance with Agenus

In January 2015Incyte and Agenus Inc. announced a global license, development and commercialization agreement focused on novel immuno-therapeutics using Agenus' proprietary Retrocyte Display™ antibody discovery platform. The pending alliance will initially focus on the development of checkpoint modulator antibodies directed against GITR, OX40, LAG-3 and TIM-3. The first clinical trials are expected to be initiated in 2016.

INCB50465 & INCB40093 – PI3Kδ Inhibitors

INCB50465, a highly potent PI3Kδ inhibitor, has now entered Phase I/II development, and INCB40093 is advancing in both monotherapy and combination proof-of-concept trials. The combination of INCB40093 and the JAK1-selective inhibitor INCB39110 is being tested in a Phase I/II trial in B-cell malignancies, and data from this study is expected in the first half of 2015.

INCB54828 – FGFR Inhibitor

The FGFR family of receptor tyrosine kinases can act as oncogenic drivers in a number of liquid and solid tumor types, most notably squamous NSCLC, gastric and bladder cancer, and glioblastoma. The Company plans to advance its selective FGFR inhibitor INCB54828 into clinical development in the first half of 2015.

INCB54329 – BRD Inhibitor

Bromodomains (BRDs) are a family of proteins which play important roles in mediating gene transcription, most notably by facilitating the expression of oncogenes such as MYC, one of the most frequently dysregulated oncogenes in all human cancer. The Company plans to begin clinical trials of INCB54329, its BRD inhibitor, in the first half of 2015.

baricitinib – JAK1 and JAK2 Inhibitor

In December 2014 the Company and Lilly announced that the Phase III RA-BEACON study of baricitinib met its primary endpoint of improved ACR20 response compared to placebo after 12 weeks of treatment. The study included patients with moderately-to-severely active rheumatoid arthritis (RA) who previously failed one or more tumor necrosis factor (TNF) inhibitors and who were taking stable doses of conventional disease-modifying anti-rheumatic drug (cDMARD) therapy. The Company and Lilly expect to share results of several other ongoing Phase III studies in various disclosures in 2015.

capmatinib (INC280) – c-MET Inhibitor

Novartis continues to make progress in the clinical development of capmatinib, a potent and selective c-MET inhibitor. Capmatinib is in two ongoing Phase II trials, the first in advanced c-MET positive hepatocellular carcinoma and the second in c-MET positive/EGFR-TKI-resistant NSCLC.

Capmatinib may have potential for use in both mono- and combination therapy regimens, including the recently announced clinical collaboration between Novartis and Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of capmatinib in an investigational combination with Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, Opdivo (nivolumab) as a potential treatment option for patients with advanced NSCLC. The investigational combination will be evaluated in a Phase II trial of patients with NSCLC.

Conference Call Information

Incyte will hold its 2014 fourth-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, 13599385.

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, 13599385.

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

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is also indicated for treatment of 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 during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

The most common side effects of Jakafi include: anemia, low platelet count, bruising, dizziness, headache.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider 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 tuberculosis (TB), or have been in close contact with someone who has TB, have or had liver or kidney problems, are on dialysis, had skin cancer 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.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 for Jakafi® (ruxolitinib), research and development expenses, and selling, general and administrative expenses; the Company's strategy and plans and expectations for the future; the Company's expectation of data from the JANUS 1 and JANUS 2 trials of ruxolitinib in second line metastatic pancreatic cancer and results from the three Phase II trials of ruxolitinib in colorectal, breast and non-small cell lung cancer in 2016; the Company's plans for INCB39110 to begin a first line pancreatic cancer study in the second half of 2015; the Company's expectation of results in the first half of 2015 from the study of INCB39110 in combination with INCB40093 in B-cell malignancies; the Company's plans to initiate both mono- and combination-therapy trials for INCB52793, potentially in multiple myeloma; the Company's expectation to initiate the first clinical trials under the Agenus alliance in 2016; the Company's plans to advance INCB54828 and INCB54329 into clinical development in the first half of 2015; and the Company's expectation to disclose with Lilly the results from other ongoing Phase III studies evaluating baricitinib in rheumatoid arthritis in 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 September 30, 2014.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Product revenues, net	$106,049	$ 72,854	$ 357,562	$235,443
Product royalty revenues	14,707	8,358	48,966	28,251
Contract revenues	3,214	15,836	104,857	91,047
Other revenues	3	24	110	206

Total revenues	123,973	97,072	511,495	354,947
Costs and expenses:				
Cost of product revenues	2,428	167	3,004	630
Research and development	98,717	75,020	347,523	260,436
Selling, general and administrative	48,452	38,028	165,772	109,983
Total costs and expenses	149,597	113,215	516,299	371,049
Loss from operations	(25,624)	(16,143)	(4,804)	(16,102)
Interest and other income, net	940	497	3,350	1,324
Interest expense	(12,516)	(8,932)	(46,828)	(38,652)
Debt exchange expense	-	(221)	(265)	(11,484)
Loss on repurchase/redemption of convertible senior notes	-	(17,934	-	(17,934)
Loss before income taxes	(37,200)	(42,733)	(48,547)	(82,848)
(Benefit) provision for income taxes	(256)	137	(66)	299
Net loss	$(36,944)	$(42,870)	$ (48,481)	$(83,147)
Net loss per basic and diluted share	$ (0.22)	$ (0.26)	$ (0.29)	$ (0.56)
Shares used in computing basic and diluted net loss per share	169,924	161,914	167,947	148,403

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(unaudited, in thousands)

	December 31, 2014	December 31, 2013
Cash, cash equivalents, and short-term marketable securities	$ 600,263	$ 509,004
Accounts receivable, net	57,933	35,374
Total assets	830,069	629,568
Convertible senior notes(1)	689,118	661,567
Total stockholders' deficit	(81,628)	(193,108)

(1) Includes short term and long term Convertible Senior Notes net of unamortized debt discount of $151.7 million and $185.0 million at December 31, 2014, and December 31, 2013, respectively.

Source: Incyte Corporation

Incyte Corporation
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