Incyte Reports 2015 Fourth-Quarter and Year-End Financial Results, Provides 2016 Financial Guidance and Updates Shareholders on Key Clinical Programs

February 11, 2016

- *$182 million of 2015 fourth-quarter net product revenues from Jakafi® (ruxolitinib), representing 72 percent growth over the same period last year and $601 million of 2015 full-year net product revenues from Jakafi, representing 68 percent growth over last year*
- *2016 guidance for Jakafi net product revenues in the range of $800 million to $815 million, reflecting expectations for continued growth in underlying demand in myelofibrosis (MF) and an increasing contribution from the ongoing launch in polycythemia vera (PV)*
- *Broad and diverse portfolio with 13 development molecules being investigated as monotherapy and in combination across multiple indications*

Conference Call and Webcast Scheduled Today at 10:00 a.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 11, 2016-- Incyte Corporation (Nasdaq: INCY) today reported 2015 fourth-quarter and year-end financial results, highlighting strong revenue growth driven by increased Jakafi® (ruxolitinib) sales in the U.S. as well as growing ex-U.S. Jakavi® (ruxolitinib) royalties from Novartis. Additionally, Incyte provided financial guidance for 2016.

Incyte's strong position in the field of JAK inhibition is demonstrated by the ongoing commercial success of Jakafi and by the recent submissions, by Eli Lilly and Company, seeking regulatory approval of baricitinib for the treatment of rheumatoid arthritis. Baricitinib was licensed to Lilly by Incyte, and met the primary endpoint in all four of its global Phase 3 studies. If approved, Lilly expects to launch baricitinib in early 2017. In addition, epacadostat, Incyte's first-in-class IDO1 inhibitor, is expected to enter Phase 3 during the first half of 2016 in first-line advanced or metastatic melanoma in combination with Merck & Co's pembrolizumab. Multiple Phase 2, tumor-specific, expansion cohorts of epacadostat in combination with anti-PD-1 and anti-PD-L1 checkpoint modulators are also underway.

"The momentum of Jakafi, now into its fifth year of commercialization, continues to be strong, and, pending regulatory approval, we look forward to a second important source of revenue from baricitinib," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "Despite the outcome of the JANUS program, our development portfolio remains robust, comprised of 13 candidates against 10 molecular targets, demonstrating Incyte's commitment to innovation and the productivity of our drug discovery and development engine."

2015 Fourth-Quarter and Full-Year Financial Results

Revenues For the quarter ended December 31, 2015, net product revenues of Jakafi were $182 million as compared to $106 million for the same period in 2014, representing 72 percent growth. For the full year ended December 31, 2015, net product revenues of Jakafi were $601 million as compared to $358 million for the same period in 2014, representing 68 percent growth. For the quarter and full year ended December 31, 2015, product royalties from sales of Jakavi outside of the United States received from Novartis were $24 million and $75 million, respectively, as compared to $15 million and $49 million, respectively, for the same periods in 2014. For the quarter ended December 31, 2015, contract revenues were $38 million as compared to $3 million for the same period in 2014. The $35 million increase in contract revenues for the quarter ended December 31, 2015 compared to the same period in 2014 relates to an increase in milestone payments earned from Novartis. For the full year ended December 31, 2015, contract revenues were $78 million as compared to $105 million for the same period in 2014. The $27 million decrease in contract revenues for the full year ended December 31, 2015 compared to the same period in 2014 relates to a decrease in milestone payments earned from Novartis. For the quarter ended December 31, 2015, total revenues were $244 million as compared to $124 million for the same period in 2014. For the full year ended December 31, 2015, total revenues were $754 million as compared to $511 million for the same period in 2014.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended December 31,		%	Twelve Months Ended December 31,		%
	2015	2014	Change	2015	2014	Change
Revenues:						
Jakafi net product revenue	$ 182,021	$ 106,049	72%	$ 601,015	$ 357,562	68%
Product royalty revenues	23,646	14,707	61%	74,821	48,966	53%
Contract and other revenues	38,214	3,217	-	77,915	104,967	-
Total revenues	$ 243,881	$ 123,973		$ 753,751	$ 511,495	

Research and development expenses Research and development expenses for the quarter and full year ended December 31, 2015 were $117 million and $480 million, respectively, as compared to $99 million and $348 million, respectively, for the same periods in 2014. Included in research and development expenses for the quarter and full year ended December 31, 2015 were non-cash expenses related to equity awards to our employees of $10 million and $40 million, respectively. The increase in research and development expenses was primarily due to the expansion of the Company's clinical portfolio, including costs related to external alliances. Also included in research and development expenses for the full year ended December 31, 2015 was the one-time upfront payment to Agenus related to our license, development and commercialization agreement and the one-time upfront payment to Jiangsu Hengrui Medicine Co., Ltd. (Hengrui) related to our global license and collaboration agreement.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter and full year ended December 31, 2015 were $52 million and $197 million, respectively, as compared to $48 million and $166 million, respectively, for the same periods in 2014. Included in selling, general and administrative expenses for the quarter and full year ended December 31, 2015 were non-cash expenses related to equity awards to our employees of $8 million and $30 million, respectively. Increased selling, general and administrative expenses are driven primarily by additional costs related to the commercialization of Jakafi.

Unrealized loss on long term investment Unrealized loss on long term investment of $0 million and $5 million, respectively, for the quarter and full year ended December 31, 2015 represents the fair market value adjustments of the Company's investment in Agenus.

Net income / (loss) Net income for the quarter ended December 31, 2015 was $55 million, or $0.30 per basic and $0.29 per diluted share, as compared to net loss of $37 million, or $0.22 per basic and diluted share, respectively, for the same period in 2014. Net income for the full year ended December 31, 2015 was $7 million, or $0.04 per basic and $0.03 per diluted share as compared to a net loss of $48 million, or $0.29 per basic and diluted share, for the same period in 2014.

Cash, cash equivalents and marketable securities position As of December 31, 2015, cash, cash equivalents and marketable securities totaled $708 million, as compared to $600 million as of December 31, 2014.

2016 Financial Guidance

The Company has provided full year 2016 financial guidance, as detailed below.

	Guidance
Jakafi net product revenues	$800-$815 million
Research and development expenses	$620-$640 million, including a non-cash expense of approximately $55-$60 million related to the impact of employee equity awards
Selling, general and administrative expenses	$255-$270 million, including a non-cash expense of approximately $30-$35 million related to the impact of employee equity awards

Portfolio Update

JAK Inhibitors

A New Drug Application (NDA) and a Marketing Authorization Application (MAA) have been submitted by Lilly to the U.S. Food and Drug Administration and the European Medicines Agency, respectively, for baricitinib, a JAK1 / JAK2 inhibitor licensed by Incyte to Lilly. These submissions triggered $35 million (NDA, as previously disclosed) and $20 million (MAA) in milestone payment obligations from Lilly to Incyte. Incyte expects to recognize both in full in the first quarter of 2016. Incyte expects to earn global regulatory milestones and will also be eligible for royalties on global net sales of baricitinib.

As previously announced, the clinical development program investigating the hypothesis that JAK inhibition may benefit patients with solid tumors and high levels of systemic inflammation has been discontinued. All commercial activities with Jakafi, and all investigational activities of JAK inhibition outside this hypothesis, are unaffected.

Ongoing studies of ruxolitinib and selective JAK1 inhibitors in hematology indications will continue. Ongoing studies of selective JAK1 inhibition in solid tumor indications that are based on different hypotheses will also continue. These include a series of combination studies evaluating INCB39110, a selective JAK1 inhibitor, with either pembrolizumab (anti-PD-1 antibody), epacadostat (Incyte's IDO1 inhibitor), or INCB50465 (Incyte's PI3Kδ inhibitor) that will assess the therapeutic utility of JAK1 inhibition based on its effects on the tumor microenvironment. Additionally, the potential for JAK1 inhibition to improve the benefit of targeted therapies will be investigated via a Phase 1/2 study of INCB39110 plus osimertinib, AstraZeneca's next generation EGFR inhibitor.

INCB39110 is also in a proof-of-concept trial for the treatment of patients with graft versus host disease.

Incyte's second selective JAK1 inhibitor, INCB52793, is in a dose escalation study in patients with advanced malignancies. INCB52793 has shown synergistic efficacy in combination with standard of care in preclinical models of multiple myeloma.

	Indication	**Status Update**
Baricitinib (JAK1/JAK2, licensed to Lilly)	Rheumatoid arthritis	NDA & MAA submitted
	Psoriasis, diabetic nephropathy	Phase 2 studies completed
	Atopic dermatitis	Phase 2
Topical ruxolitinib (JAK1/JAK2)[1]	Alopecia areata	Phase 2

INCB39110 (JAK1)	Lung cancer	Phase 1/2 in combination with osimertinib (EGFR) expected to initiate mid-year 2016
	Advanced malignancies	Phase 1/2 in combination with pembrolizumab (PD-1), epacadostat (IDO1), or INCB50465 (PI3Kδ)
	Graft versus host disease	Phase 2
INCB52793 (JAK1)	Advanced malignancies	Phase 1/2

[1] The Collaboration and License Agreement with Novartis for ruxolitinib ex-U.S. does not include topical administration.

IDO1 Inhibitor

The ECHO (Epacadostat Clinical development in Hematology and Oncology) program has been designed to investigate combinations of Incyte's IDO1 inhibitor, epacadostat, across the full cycle of anti-tumor immunity, including with checkpoint blockade, vaccines and other modulators of the tumor immune response.

The Phase 3 ECHO-301 study evaluating the combination of epacadostat with the anti-PD-1 antibody pembrolizumab for the first-line treatment of patients with advanced or metastatic melanoma is expected to begin in the first half of 2016.

During 2016, Incyte expects to have recruited over 600 patients into Phase 2 expansion cohorts investigating the safety and efficacy of epacadostat in combination with anti-PD-1 and anti-PD-L1 agents.

	Indication	**Status Update**
Epacadostat	First line, advanced melanoma	Phase 3 (ECHO-301) expected to begin in the first half of 2016 in combination with pembrolizumab (PD-1)
	Multiple tumor types	Phase 2 (ECHO-202) expansion cohorts now recruiting in combination with pembrolizumab (PD-1)
	Multiple tumor types	Phase 2 (ECHO-204) expansion cohorts now recruiting in combination with nivolumab (PD-1)
	Multiple tumor types	Phase 2 (ECHO-203) expansion cohorts now recruiting in combination with durvalumab (PD-L1)
	Non-small cell lung cancer	Phase 1/2 (ECHO-110) dose-escalation ongoing in combination with atezolizumab (PD-L1)

Additional Programs

With two of our new programs expected to enter the clinic in the coming months, Incyte will have a total of 13 development molecules in pivotal and proof-of-concept trials across a variety of oncology and non-oncology indications. Below is a portfolio summary, in addition to Incyte's JAK inhibitor franchise and its IDO1 inhibitor epacadostat.

	Indication	**Status Update**
INCB50465 (PI3Kδ)	B-cell malignancies	Phase 1/2 as monotherapy and in combination with INCB39110 (JAK1); expansion cohorts initiating
	Solid tumors	Phase 1/2 in combination with pembrolizumab (PD-1), epacadostat (IDO1), or INCB39110 (JAK1)
Capmatinib (c-MET, licensed to Novartis)	Non-small cell lung cancer, glioblastoma, liver cancer	Phase 2 in patients with c-MET amplification
INCB54828 (FGFR)	Solid tumors	Phase 1/2 dose escalation; expansion cohorts in genetically-defined tumor types expected in 2016
INCB54329 (BRD)	Advanced malignancies	Phase 1/2 dose-escalation
INCB53914 (PIM)	Advanced malignancies	Phase 1/2 dose-escalation
INCSHR1210 (PD-1, licensed from Hengrui)	Solid tumors	Phase 1/2 dose-escalation
INCB59872 (LSD1)	Advanced malignancies	Phase 1/2 expected to initiate in the first half of 2016
INCAGN1876 (GITR, co-developed with Agenus)	Advanced malignancies	Phase 1/2 expected to initiate in the first half of 2016

Conference Call and Webcast Information

Incyte will hold its 2015 fourth-quarter and year-end financial results conference call and webcast this morning at 10:00 a.m. ET. To access the conference call, please dial 877-407-9221 for domestic callers or 201-689-8597 for international callers. When prompted, provide the conference identification number, 13628695.

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, 13628695.

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. 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.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the Company's financial guidance for 2016 and the expectations underlying such guidance; whether and when the Company will receive earned and future potential regulatory milestone payments or royalty payments from Lilly with respect to baricitinib, whether baricitinib will be approved in the U.S. or receive a positive opinion in Europe, and whether and when Lilly will launch baricitinib; whether stopping the solid tumor studies of ruxolitinib will impact commercial activities with Jakafi, studies of JAK inhibition or other ongoing studies of JAK1 inhibition in solid tumors; the potential success of the studies of ruxolitinib and selective JAK1 inhibitors in hematology indications and other solid tumor indications; plans regarding the Company's product pipeline and strategy, and plans and expected timelines for advancing its drug candidates through clinical trials, including enrollment, and regulatory submissions and for releasing trial data, including, without limitation, its selective JAK1 inhibitor, IDO1 inhibitor, FGFR inhibitor, BRD inhibitor, GITR, LSD1, PI3K-delta, PD-1 and PIM programs.

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 and risks associated with 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 or warrant continued development, 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, greater than expected expenses, unanticipated or unpredictable expenses relating to litigation or strategic activities, our ability to obtain additional capital when needed, risks related to obtaining effective patent coverage for our products 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, 2015. The Company disclaims any intent or obligation to update these forward-looking statements.

INCYTE CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Revenues:				
Product revenues, net	$182,021	$106,049	$ 601,015	$ 357,562
Product royalty revenues	23,646	14,707	74,821	48,966
Contract revenues	38,214	3,214	77,857	104,857
Other revenues	-	3	58	110
Total revenues	243,881	123,973	753,751	511,495
Costs and expenses:				
Cost of product revenues	9,704	2,428	26,972	3,004
Research and development	116,630	98,717	479,514	347,523
Selling, general and administrative	52,467	48,452	196,614	165,772
Total costs and expenses	178,801	149,597	703,100	516,299
Income (loss) from operations	65,080	(25,624)	50,651	(4,804)
Interest and other income, net	1,289	940	7,089	3,350
Interest expense	(10,213)	(12,516)	(45,603)	(46,828)
Unrealized loss on long term investment	(466)	-	(4,581)	-
Debt exchange expense on senior note conversions	-	-	-	(265)
Income (loss) before provision for income taxes	55,690	(37,200)	7,556	(48,547)
Provision (benefit) for income taxes	512	(256)	1,025	(66)
Net income (loss)	$ 55,178	$ (36,944	$ 6,531	$ (48,481

Net income (loss) per share:				
Basic	$ 0.30	$ (0.22)	$ 0.04	$ (0.29)
Diluted	$ 0.29	$ (0.22)	$ 0.03	$ (0.29)
Shares used in computing net income (loss) per share:				
Basic	186,269	169,924	179,601	167,947
Diluted	193,367	169,924	187,302	167,947

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31, 2015	December 31, 2014
ASSETS		
Cash, cash equivalents and marketable securities	$ 707,783	$ 600,263
Restricted cash and investments	14,493	14,500
Accounts receivable	114,450	57,933
Property and equipment, net	86,006	81,790
Inventory	19,338	19,436
Prepaid expenses and other assets	30,122	22,555
Long term investment	35,248	-
Total assets	$ 1,007,440	$ 796,477
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable, accrued expenses and other liabilities	$ 203,880	$ 177,547
Deferred revenue—collaborative agreements	12,512	25,391
Convertible senior notes	619,893	675,167
Stockholders' equity (deficit)	171,155	(81,628)
Total liabilities and stockholders' equity (deficit)	$ 1,007,440	$ 796,477

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Source: Incyte Corporation

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