Incyte Reports 2015 Third-Quarter Financial Results and Updates Shareholders on Key Clinical Programs

November 3, 2015

- $161 million of 2015 third-quarter net product revenues from Jakafi® (ruxolitinib), representing 65 percent growth over the same period last year

- Positive results from two pivotal trials of baricitinib to be highlighted at ACR; baricitinib superior to both methotrexate (RA-BEGIN) and to Humira® (adalimumab) (RA-BEAM) in reducing the signs and symptoms of rheumatoid arthritis

- Agreement announced with Merck to expand clinical collaboration to include a pivotal trial of epacadostat plus pembrolizumab in first-line advanced or metastatic melanoma; proof-of-concept data from the ongoing Phase I/II trial to be presented at SITC

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

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 3, 2015-- Incyte Corporation (Nasdaq: INCY) today reported 2015 third-quarter financial results, including revenue from Jakafi.

The Company highlighted the continued strong revenue growth from Jakafi in the U.S. and royalties from sales of Jakavi® (ruxolitinib) outside of the U.S. by the Company's collaborator, Novartis, as well as significant progress across its development portfolio. During November 2015, Incyte expects detailed data from the remaining two Phase III trials of the global registration program for baricitinib in patients with rheumatoid arthritis (RA) to be presented at the American College of Rheumatology (ACR), as well as the first presentation of data from the proof-of-concept trial of epacadostat, Incyte's selective IDO1 inhibitor, in combination with Merck's anti-PD-1 antibody, pembrolizumab, at the Society for Immunotherapy of Cancer (SITC). The Company recently announced an agreement with Merck to expand their clinical collaboration to include a pivotal trial of epacadostat plus pembrolizumab in first-line advanced or metastatic melanoma. Incyte has also recently initiated clinical trials of INCSHR1210, an anti-PD-1 monoclonal antibody, in patients with solid tumors, INCB53914, a selective pan-PIM kinase inhibitor, in hematological malignancies and topical ruxolitinib cream for the treatment of patients with alopecia areata.

"We are very pleased with the continued revenue growth from Jakafi during the third quarter, which was driven by strong underlying demand from both of its approved indications," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "We are successfully executing on our aggressive clinical development plans, and believe that the positive outcome of the pivotal RA development program for baricitinib and the progression of epacadostat into a global Phase III trial are both landmark events as we continue our transformation into a world-leading biopharmaceutical business."

2015 Third-Quarter Financial Results

Revenues For the quarter ended September 30, 2015, net product revenues of Jakafi were $161 million as compared to $98 million for the same period in 2014, representing 65 percent growth. For the nine months ended September 30, 2015, net product revenues of Jakafi were $419 million as compared to $252 million for the same period in 2014, representing 67 percent growth. For the quarter and nine months ended September 30, 2015, product royalties from sales of Jakavi outside of the United States received from Novartis were $18 million and $51 million, respectively, as compared to $12 million and $34 million, respectively, for the same periods in 2014. For the quarter ended September 30, 2015, contract revenues were $8 million as compared to $88 million for the same period in 2014. For the nine months ended September 30, 2015, contract revenues were $40 million as compared to $102 million for the same period in 2014. The $62 million decrease in contract revenues for the nine months ended September 30, 2015 compared to the same period in 2014 relates to a decrease in milestone payments earned from Novartis. For the quarter ended September 30, 2015, total revenues were $188 million as compared to $198 million for the same period in 2014. For the nine months ended September 30, 2015, total revenues were $510 million as compared to $388 million for the same period in 2014.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2015	2014	Change	2015	2014	Change
Revenues:						
Jakafi net product revenue	$ 161,259	$ 97,837	65%	$ 418,994	$ 251,513	67%
Product royalty revenues	18,138	12,093	50%	51,175	34,259	49%
Contract revenues	8,214	88,214	-	39,643	101,643	-
Other revenues	-	3	-	58	107	-
Total revenues	$ 187,611	$ 198,147		$ 509,870	$ 387,522	

Research and development expenses Research and development expenses for the quarter and nine months ended September 30, 2015 were $132 million and $363 million, respectively, as compared to $89 million and $249 million, respectively, for the same periods in 2014. Included in research and development expenses for the quarter and nine months ended September 30, 2015 were non-cash expenses related to equity awards to our employees of $10 million and $30 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 nine months ended September 30, 2015 was the one-time upfront payment to Agenus related to our license, development and commercialization agreement and for the quarter and nine months ended September 30, 2015, the one-time upfront payment to Jiangsu Hengrui Medicine Co., Ltd. related to our global license and collaboration agreement.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter and nine months ended September 30, 2015 were $48 million and $144 million, respectively, as compared to $39 million and $117 million, respectively, for the same periods in 2014. Included in selling, general and administrative expenses for the quarter and nine months ended September 30, 2015 were non-cash expenses related to equity awards to our employees of $8 million and $22 million respectively. Increased selling, general and administrative expenses reflected additional costs related to the commercialization of Jakafi.

Unrealized loss on long term investment Unrealized loss on long term investment of $31 million and $4 million, respectively, for the quarter and nine months ended September 30, 2015 represents the fair market value adjustments of the Company's investment in Agenus.

Net income / (loss) Net loss for the quarter ended September 30, 2015 was $40 million, or $0.22 per basic and diluted share, as compared to net income of $59 million, or $0.35 and $0.33 per basic and diluted share, respectively, for the same period in 2014. Net loss for the nine months ended September 30, 2015 was $49 million, or $0.27 per basic and diluted share as compared to a net loss of $12 million, or $0.07 per basic and diluted share, for the same period in 2014.

Cash, cash equivalents and marketable securities position As of September 30, 2015, cash, cash equivalents and marketable securities totaled $635 million, as compared to $600 million as of December 31, 2014.

2015 Financial Guidance

The Company has updated its full year 2015 financial guidance, as detailed below.

	Previous Guidance	**Updated Guidance**
Jakafi net product revenues	$560-$575 million	$580-$590 million
Contract revenue (including milestone revenues)	$58 million	$78 million
Research and development expenses	$475-$500 million, includes non-cash stock compensation expense of $40-$45 million	Unchanged
Selling, general and administrative expenses	$195-$210 million, includes non-cash compensation expense of $30-$35 million	$200-$210 million, includes non-cash compensation expense of $30-$35 million

Product Update

Jakafi (ruxolitinib) – JAK1 and JAK2 Inhibitor

The pivotal Phase III JANUS 1 and JANUS 2 studies of ruxolitinib in second line metastatic pancreatic cancer are ongoing. Three Phase II trials of ruxolitinib are ongoing in colorectal, breast and non-small cell lung cancer (NSCLC) patients.

A Phase II trial of topical ruxolitinib cream has begun in patients with alopecia areata, the primary endpoint of which is the percentage of subjects achieving a Severity of Alopecia Tool score (SALT) 50 response in terminal hair (pigmented and non-pigmented) at 24 weeks.

baricitinib – JAK1 and JAK2 Inhibitor

In September 2015, the Company and Eli Lilly and Company ("Lilly") announced that the Phase III RA-BEGIN study of baricitinib met its primary endpoint of non-inferiority of baricitinib monotherapy to methotrexate monotherapy based on ACR20 response rate after 24 weeks of treatment. Additionally, baricitinib was superior to methotrexate based on ACR20 response. The RA-BEGIN study included RA patients who had limited or no prior treatment with methotrexate, and were naïve to other conventional or biologic disease-modifying antirheumatic drugs (DMARDs).

In October 2015, the Company and Lilly announced that the Phase III RA-BEAM study of baricitinib met its primary endpoint of improved ACR20 response compared to placebo after 12 weeks of treatment. The RA-BEAM study also included an active comparator group of RA patients taking Humira® (adalimumab)*, and all patients were also treated with background methotrexate. The results of the RA-BEAM trial also showed that baricitinib was superior to adalimumab on key secondary objectives of ACR20 response and improvement in DAS28-hsCRP score after 12 weeks of treatment, and that following 24 weeks of treatment, baricitinib was superior to placebo in preventing progressive radiographic structural joint damage.

epacadostat (INCB24360) – IDO1 Inhibitor

Four clinical trials to evaluate epacadostat in combination with immune checkpoint inhibitors are all recruiting patients. These trials are evaluating epacadostat in combination with Merck & Co's PD-1 inhibitor Keytruda ® (pembrolizumab)*, AstraZeneca/MedImmune's investigational PD-L1 inhibitor, durvalumab, Bristol-Myers Squibb's PD-1 inhibitor, Opdivo ® (nivolumab)*, and Roche/Genentech's investigational PD-L1 inhibitor, atezolizumab.

Initial proof-of-concept results from the combination trial of epacadostat and pembrolizumab are expected to be presented at the upcoming Society for Immunotherapy of Cancer (SITC) 30th Anniversary Annual Meeting & Associated Programs on November 6.

In October 2015, the Company and Merck & Co. announced an expansion of the companies' ongoing clinical collaboration to include a Phase III study evaluating the combination of epacadostat with pembrolizumab as a first-line treatment for patients with advanced or metastatic melanoma.

INCB39110 & INCB52793 – JAK1-Selective Inhibitors

INCB39110, in combination with INCB40093, Incyte's PI3Kδ inhibitor, is in development for patients with B-cell malignancies. INCB39110 is also in a Phase II trial, in combination with gemcitabine and nab-paclitaxel, in patients with pancreatic cancer.

The Company's second JAK1-selective inhibitor, INCB52793, is in a Phase I/II monotherapy dose-escalation trial in advanced malignancies.

INCB40093 & INCB50465 – PI3Kδ Inhibitors

INCB40093 is in clinical development in combination with the JAK1-selective inhibitor INCB39110 in B-cell malignancies. An open-label, dose-escalation monotherapy study of INCB50465 in subjects with previously treated B-cell malignancies is underway.

capmatinib (INC280) – c-MET Inhibitor

Capmatinib is being investigated by Novartis in a variety of solid tumors, including advanced c-MET positive hepatocellular carcinoma, c-MET positive/EGFR-TKI-resistant NSCLC and glioblastoma multiforme, as well as in combination, including with Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, nivolumab, in a Phase II trial of patients with NSCLC.

INCB54828 – FGFR Inhibitor

INCB54828 is in an open-label, dose-escalation study in subjects with advanced malignancies.

INCB54329 – BRD Inhibitor

INCB54329 is in an open-label, dose-escalation study in subjects with advanced malignancies.

INCSHR1210 – PD-1 inhibitor

During the third quarter of 2015, Incyte announced a global license and collaboration agreement with Jiangsu Hengrui Medicine Co., Ltd. for the development and commercialization of SHR-1210 (now INCSHR1210), an investigational anti-PD-1 monoclonal antibody. INCSHR1210 has now entered a proof-of-concept trial for the treatment of patients with advanced solid tumors.

INCB53914 – PIM Inhibitor

The Company has initiated an open-label, dose-escalation study of INCB53914, a selective pan-PIM kinase inhibitor, in subjects with hematological malignancies.

Conference Call and Webcast Information

Incyte will hold its 2015 third-quarter 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, 13622010.

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, 13622010.

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.

* The brand listed is not a trademark of Incyte Corporation. The maker of this brand is not affiliated with and does not endorse Incyte Corporation or its products.

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 2015; its continued transformation into a world-leading biopharmaceutical business; and the Company's emerging development pipeline and the timing and potential success of any of those studies as well as the Company's and, where applicable, its and its collaborators' plans to announce data from any of those studies.

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, 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 September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Product revenues, net	$161,259	$ 97,837	$418,994	$251,513
Product royalty revenues	18,138	12,093	51,175	34,259
Contract revenues	8,214	88,214	39,643	101,643
Other revenues	-	3	58	107
Total revenues	187,611	198,147	509,870	387,522
Costs and expenses:				
Cost of product revenues	8,040	221	17,268	576
Research and development	132,073	88,537	362,882	248,806
Selling, general and administrative	47,599	39,446	144,147	117,320
Total costs and expenses	187,712	128,204	524,297	366,702
Income (loss) from operations	(101)	69,943	(14,427)	20,820
Interest and other income, net	3,026	885	5,800	2,410
Interest expense	(11,209)	(11,463)	(35,390)	(34,312)
Unrealized loss on long term investment	(31,289)	-	(4,115)	-
Debt exchange expense on senior note conversions	-	-	-	(265)
Income (loss) before provision for income taxes	(39,573)	59,365	(48,132)	(11,347)
Provision for income taxes	9	72	513	191
Net income (loss)	$(39,582)	$ 59,293	$(48,645)	$(11,538)
Net income (loss) per share:				
Basic	$ (0.22)	$ 0.35	$ (0.27)	$ (0.07)
Diluted	$ (0.22)	$ 0.33	$ (0.27)	$ (0.07)
Shares used in computing net income (loss) per share:				
Basic	181,387	168,592	177,378	167,288
Diluted	181,387	189,046	177,378	167,288

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2015 (unaudited)	December 31, 2014 (audited)
ASSETS		
Cash, cash equivalents and marketable securities	$ 635,045	$ 600,263
Restricted cash and investments	18,628	14,500
Accounts receivable	86,966	57,933
Property and equipment, net	83,186	81,790
Inventory	20,266	19,436
Prepaid expenses and other assets	52,127	56,147
Long term investment	35,714	-
Total assets	$ 931,932	$ 830,069
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable, accrued expenses and other liabilities	$ 203,536	$ 197,188
Deferred revenue—collaborative agreements	15,726	25,391

Convertible senior notes	623,933	689,118
Stockholders' equity (deficit)	88,737	(81,628)
Total liabilities and stockholders' equity (deficit)	$ 931,932	$ 830,069

View source version on businesswire.com: http://www.businesswire.com/news/home/20151103005312/en/

Source: Incyte Corporation

Incyte Corporation
Media
Catalina Loveman, +1 302-498-6171
cloveman@incyte.com
or
Investors
Michael Booth, DPhil, +1 302-498-5914
mbooth@incyte.com