

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

August 4, 2015

- \$142 million of 2015 second-quarter net product revenues from Jakafi® (ruxolitinib), representing 69 percent growth over the same period last year
- 2015 guidance for Jakafi net product revenues increased to range of \$560 million to \$575 million, driven by strong underlying demand
- Positive results from two pivotal trials of baricitinib in rheumatoid arthritis presented at EULAR
- Multiple abstracts presented at ASCO and EHA, demonstrating continued progress across broad clinical portfolio

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 4, 2015-- Incyte Corporation (Nasdaq: INCY) today reported 2015 second-quarter financial results, including revenue from Jakafi.

The Company highlighted the continued momentum in the commercialization of Jakafi in the U.S., as well as progress being made across its clinical portfolio, including the results of two pivotal trials of baricitinib that were presented with Eli Lilly and Company ("Lilly") at the 2015 European League Against Rheumatism (EULAR) meeting in June. In addition, positive proof-of-concept results from the novel combination of Incyte's PI3Kδ inhibitor INCB40093 and JAK1-selective inhibitor INCB39110 in B-cell malignancies were presented at both the 2015 American Society of Clinical Oncology(ASCO) and European Hematology Association (EHA) annual meetings in the second quarter of 2015.

"The commercial performance of Jakafi in Q2 2015 was very strong, confirming both underlying growth from the myelofibrosis indication and an acceleration in Jakafi growth from the launch in patients with uncontrolled polycythemia vera," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "Recent data presented from our product candidates, and the progress we are making in recruiting multiple clinical trials, further illustrate the strength and diversity of our development portfolio."

Jakafi is 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.

2015 Second-Quarter Financial Results

Revenues For the quarter ended June 30, 2015, net product revenues of Jakafi were \$142 million as compared to \$84 million for the same period in 2014, representing 69 percent growth. For the six months ended June 30, 2015, net product revenues of Jakafi were \$258 million as compared to \$154 million for the same period in 2014, representing 68 percent growth. For the quarter and six months ended June 30, 2015, product royalties from sales of Jakafi® (ruxolitinib) outside of the United States received from Novartis, the Company's collaborator, were \$17 million and \$33 million, respectively, as compared to \$12 million and \$22 million, respectively, for the same periods in 2014. For the quarter ended June 30, 2015, contract revenues were \$3 million as compared to \$3 million for the same period in 2014. For the six months ended June 30, 2015, contract revenues were \$31 million as compared to \$13 million for the same period in 2014. The \$18 million increase in contract revenues for the six months ended June 30, 2015 compared to the same period in 2014 relates to an increase in milestone payments earned from Novartis. For the quarter ended June 30, 2015, total revenues were \$163 million as compared to \$100 million for the same period in 2014. For the six months ended June 30, 2015, total revenues were \$322 million as compared to \$189 million for the same period in 2014.

Year Over Year Revenue Growth (in thousands, unaudited)

	Three Months Ended			Six Months Ended		
	June 30,		%	June 30,		%
	2015	2014	Change	2015	2014	Change
Revenues:						
Jakafi net product revenue	\$142,406	\$ 84,025	69%	\$257,736	\$153,676	68%
Product royalty revenues	17,364	12,340	41%	33,037	22,166	49%
Contract revenues	3,214	3,214	-	31,429	13,429	-
Other revenues	-	3	-	58	103	-
Total revenues	<u>\$162,984</u>	<u>\$ 99,582</u>		<u>\$322,260</u>	<u>\$189,374</u>	

Research and development expenses Research and development expenses for the quarter and six months ended June 30, 2015 were \$112 million and \$231 million, respectively, as compared to \$85 million and \$160 million, respectively, for the same periods in 2014. Included in research and

development expenses for the quarter and six months ended June 30, 2015 were non-cash expenses related to equity awards to our employees of \$10 million and \$20 million respectively. The increase in research and development expenses was primarily due to the expansion of the Company's clinical portfolio. Also included in research and development expenses for the six months ended June 30, 2015 was the one-time upfront payment to Agenus related to our license, development and commercialization agreement.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter and six months ended June 30, 2015 were \$52 million and \$97 million, respectively, as compared to \$41 million and \$78 million, respectively, for the same periods in 2014. Included in selling, general and administrative expenses for the quarter and six months ended June 30, 2015 were non-cash expenses related to equity awards to our employees of \$7 million and \$15 million respectively. Increased selling, general and administrative expenses reflected additional costs related to the commercialization of Jakafi.

Unrealized gain on long term investment Unrealized gain on long term investment of \$27 million for the quarter and six months ended June 30, 2015 represents the fair market value adjustment of the Company's investment in Agenus.

Net income / (loss) Net income for the quarter ended June 30, 2015 was \$9 million, or \$0.05 per basic and diluted share, as compared to a net loss of \$37 million, or \$0.22 per basic and diluted share, for the same period in 2014. Net loss for the six months ended June 30, 2015 was \$9 million, or \$0.05 per basic and diluted share as compared to a net loss of \$71 million, or \$0.43 per basic and diluted share, for the same period in 2014.

Cash, cash equivalents and marketable securities position As of June 30, 2015, cash, cash equivalents and marketable securities totaled \$627 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	\$525-\$565 million	\$560-\$575 million
Research and development expenses	\$450-\$500 million, includes non-cash stock compensation expense of \$40-\$45 million	\$475-\$500 million, includes non-cash stock compensation expense of \$40-\$45 million
Selling, general and administrative expenses	\$180-200 million, includes non-cash stock compensation expense of \$30-\$35 million	\$195-\$210 million, includes non-cash compensation expense of \$30-\$35 million

Product Update

Jakafi (ruxolitinib) – JAK1 and JAK2 Inhibitor

Follow-up results from the pivotal RESPONSE trial of ruxolitinib in patients with uncontrolled polycythemia vera were presented at the 2015 ASCO meeting, showing 83% of patients were still receiving ruxolitinib at a median exposure of 111 weeks.

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.

baricitinib – JAK1 and JAK2 Inhibitor

In June 2015, the Company and Lilly presented five abstracts for baricitinib, including oral presentations of data from the pivotal RA-BEACON and RA-BUILD studies, at the 2015 EULAR meeting. The Company and Lilly expect to share results of two further Phase III studies in various disclosures in late 2015.

In April 2015, positive proof-of-concept data for baricitinib for the treatment of patients with diabetic nephropathy (diabetic kidney disease) were presented by Lilly at the scientific sessions of the American Diabetes Association.

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, MEDI4736, Bristol-Myers Squibb's PD-1 inhibitor, Opdivo[®] (nivolumab), and Roche/Genentech's investigational PD-L1 inhibitor, MPDL3280A.

INCB39110 & INCB52793 – JAK1-Selective Inhibitors

In May 2015, initial results of the combination of INCB39110 plus INCB40093, Incyte's PI3K δ inhibitor, in patients with B-cell malignancies were presented at the 2015 ASCO meeting. INCB39110 is also in a Phase II trial in NSCLC patients, in combination with erlotinib, and 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 – PI3K δ Inhibitors

Initial results of the combination of INCB40093 and the JAK1-selective inhibitor INCB39110 in B-cell malignancies were presented at the 2015 ASCO meeting.

INCB50465 is a highly-potent PI3K δ inhibitor, and an open-label, dose-escalation study of INCB50465 in subjects with previously treated B-cell malignancies has been initiated.

capmatinib (INC280) – c-MET Inhibitor

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

In the second quarter of 2015, the Company initiated an open-label, dose-escalation study of INCB54329 in subjects with advanced malignancies.

Conference Call and Webcast Information

Incyte will hold its 2015 second-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, 13611732.

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, 13611732.

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.

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; the Company's emerging development pipeline and the timing and potential success of any of those studies; and the Company's expectation to disclose, with Lilly, the results from other ongoing Phase III studies evaluating baricitinib in rheumatoid arthritis in 2015.

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 March 31, 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		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Revenues:				
Product revenues, net	\$142,406	\$ 84,025	\$257,736	\$153,676
Product royalty revenues	17,364	12,340	33,037	22,166
Contract revenues	3,214	3,214	31,429	13,429
Other revenues	-	3	58	103
Total revenues	<u>162,984</u>	<u>99,582</u>	<u>322,260</u>	<u>189,374</u>
Costs and expenses:				
Cost of product revenues	6,254	187	9,229	355
Research and development	112,445	84,683	230,809	160,269

Selling, general and administrative	51,679	40,899	96,548	77,873
Total costs and expenses	<u>170,378</u>	<u>125,769</u>	<u>336,586</u>	<u>238,497</u>
Loss from operations	(7,394)	(26,187)	(14,326)	(49,123)
Interest and other income, net	1,144	790	2,773	1,526
Interest expense	(11,494)	(11,406)	(24,181)	(22,849)
Unrealized gain on long term investment	27,174	-	27,174	-
Debt exchange expense on senior note conversions	-	-	-	(265)
Income (loss) before provision for income taxes	9,430	(36,803)	(8,560)	(70,711)
Provision for income taxes	136	70	503	119
Net income (loss)	<u>\$ 9,294</u>	<u>\$(36,873)</u>	<u>\$ (9,063)</u>	<u>\$(70,830)</u>

Net income (loss) per share:

Basic	\$ 0.05	\$ (0.22)	\$ (0.05)	\$ (0.43)
Diluted	\$ 0.05	\$ (0.22)	\$ (0.05)	\$ (0.43)

Shares used in computing net income (loss) per share:

Basic	178,676	167,914	175,373	166,636
Diluted	186,493	167,914	175,373	166,636

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2015 (unaudited)	December 31, 2014 (audited)
ASSETS		
Cash, cash equivalents and marketable securities	\$ 627,469	\$ 600,263
Restricted investments	14,773	14,500
Accounts receivable	75,122	57,933
Property and equipment, net	81,602	81,790
Inventory	20,445	19,436
Prepaid expenses and other assets	43,923	56,147
Long term investment	67,003	-
Total assets	<u>\$ 930,337</u>	<u>\$ 830,069</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable, accrued expenses and other liabilities	\$ 196,258	\$ 197,188
Deferred revenue—collaborative agreements	18,940	25,391
Convertible senior notes	659,965	689,118
Stockholders' equity (deficit)	55,174	(81,628)
Total liabilities and stockholders' equity (deficit)	<u>\$ 930,337</u>	<u>\$ 830,069</u>

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Source: Incyte Corporation

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