Incyte Reports 2016 First-Quarter Financial Results and Updates Shareholders on Key Clinical Programs

May 9, 2016

- *$183 million of 2016 first-quarter net product revenues from Jakafi® (ruxolitinib), representing 59 percent growth over the same period last year. Full year Jakafi net product revenue guidance increased from a range of $800-815 million to a range of $815-830 million.*
- *Recent agreements with Lilly and Novartis allow development of ruxolitinib for the treatment of graft versus host disease (GVHD); U.S. pivotal trial expected to begin in the second half of 2016.*
- *Expanded European organization via acquisition of ARIAD Pharmaceuticals' European business*
- *Diversified and growing portfolio of cancer therapies highlighted in multiple presentations at the AACR annual meeting.*

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

WILMINGTON, Del.--(BUSINESS WIRE)--May 9, 2016-- Incyte Corporation (Nasdaq: INCY) today reported 2016 first-quarter financial results, including strong revenue growth driven by increased Jakafi® (ruxolitinib) sales in the U.S. as well as continued growth in ex-U.S. Jakavi® (ruxolitinib) royalties from Novartis.

Incyte's broad portfolio of development candidates includes immuno-oncology as well as targeted anti-cancer therapies and is made up of both small and large molecules. The recent presentations at the 2016 annual meeting of the American Association of Cancer Research (AACR) showcased the depth of Incyte's discovery and development expertise, including both monotherapy and combination therapy approaches.

As also announced today, Incyte has agreed to acquire the European operations of ARIAD Pharmaceuticals and the development and commercialization rights to Iclusig® (ponatinib) in Europe. The acquisition of a fully-integrated and established pan-European team, including medical, sales and marketing personnel, will help Incyte optimize clinical development and maximize the potential of future European launches for its portfolio of products.

"Incyte has a unique profile within the biopharmaceutical industry. Our revenue growth and the underlying demand for Jakafi are strong, and we also have the potential for a second important source of revenue should baricitinib be approved in 2017," stated Hervé Hoppenot, Incyte's Chief Executive Officer. "We have a fast-moving and rapidly expanding portfolio of exciting development projects, and we also look forward to the initiation of two new pivotal programs – epacadostat for the 1st line treatment of advanced melanoma and ruxolitinib for the treatment of graft versus host disease – during 2016."

2016 First-Quarter Financial Results

Revenues For the quarter ended March 31, 2016, net product revenues of Jakafi were $183 million as compared to $115 million for the same period in 2015, representing 59 percent growth. For the quarter ended March 31, 2016, product royalties from sales of Jakavi outside of the United States received from Novartis were $22 million as compared to $16 million for the same period in 2015. For the quarter ended March 31, 2016, contract revenues were $58 million as compared to $28 million for the same period in 2015. We earned $55 million in milestone payments from Lilly during the quarter ended March 31, 2016 and a $25 million milestone payment from Novartis during the quarter ended March 31, 2015. For the quarter ended March 31, 2016, total revenues were $263 million as compared to $159 million for the same period in 2015.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended March 31,		%
	2016	2015	Change
Revenues:			
Jakafi net product revenue	$ 183,267	$ 115,330	59%
Product royalty revenues	21,903	15,673	40%
Contract revenues	58,214	28,214	-
Other revenues	80	58	-
Total revenues	$ 263,464	$ 159,275	

Research and development expenses Research and development expenses for the quarter ended March 31, 2016 were $157 million as compared to $118 million for the same period in 2015. Included in research and development expenses for the quarter ended March 31, 2016 is the previously announced $35 million upfront payment to acquire the rights from Lilly to develop ruxolitinib for the treatment of patients with GVHD and non-cash

expenses related to equity awards to our employees of $13 million. In addition to the $35 million upfront payment to Lilly, the increase in research and development expenses was primarily due to the expansion of the Company's clinical portfolio.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter ended March 31, 2016 were $65 million as compared to $45 million for the same period in 2015. Included in selling, general and administrative expenses for the quarter ended March 31, 2016 were non-cash expenses related to equity awards to our employees of $8 million. 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 $3 million for the quarter ended March 31, 2016 represents the fair market value adjustments of the Company's investment in Agenus.

Net income / (loss) Net income for the quarter ended March 31, 2016 was $24 million, or $0.13 per basic and $0.12 per diluted share, as compared to net loss of $18 million, or $0.11 per basic and diluted share for the same period in 2015.

Cash, cash equivalents and marketable securities position As of March 31, 2016, cash, cash equivalents and marketable securities totaled $811 million, as compared to $708 million as of December 31, 2015.

2016 Financial Guidance

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

	Incyte	ARIAD EU	Combined
Jakafi net product revenues	$815-$830 million (previously $800-$815 million)	-	**$815-$830 million**
Iclusig net product revenues	-	$25-$30 million	**$25-$30 million**
Research and development expenses	$620-$640 million (no change)	$15-$20 million	**$635-$660 million**
Selling, general and administrative expenses	$255-$275 million (previously $255-$270 million)	$30-$35 million	**$285-$310 million**

Corporate Update

In May 2016, Dr. Vijay Iyengar joined the Incyte Executive Management team as Head of Global Product Strategy, a position from which he will also lead Incyte's business development, licensing and strategic planning teams. Vijay was previously President, Genoptix Corporation, a Novartis Company, and has significant international biopharma experience in building and managing teams in the U.S. and in Europe.

Portfolio Update

Targeted Cancer Therapies

In April, preliminary data from an open-label Phase 1 dose escalation trial of INCB50465, Incyte's second-generation, highly selective PI3K delta inhibitor, was presented at AACR 2016. INCB50465 showed promising efficacy in B-cell malignancies and was generally well tolerated at all doses tested.

	Indication	Status Update
INCB50465 (PI3Kδ)	B-cell malignancies	Phase 1/2 as monotherapy and in combination with INCB39110 (JAK1); expansion cohorts initiating
INCB39110 (JAK1)	Lung cancer	Phase 1/2 in combination with osimertinib (EGFR) expected to initiate mid-year 2016
INCB52793 (JAK1)	Advanced malignancies	Phase 1/2 dose-escalation
Capmatinib (c-MET, licensed to Novartis)	Non-small cell lung cancer, glioblastoma, liver cancer	Phase 2 in EGFR wild-type ALK negative NSCLC patients with c-MET amplification and mutation
INCB54828 (FGFR)	Advanced malignancies	Phase 1/2 dose escalation; expansion cohorts in genetically-defined tumor types now underway
INCB54329 (BRD)	Advanced malignancies	Phase 1/2 dose-escalation
INCB53914 (PIM)	Advanced malignancies	Phase 1/2 dose-escalation
INCB59872 (LSD1)	Acute myeloid leukemia, small cell lung cancer	Phase 1/2 dose-escalation

Immune Cancer Therapies

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. The trial, randomized, double-blind and placebo controlled, is planned to enroll 600 patients and to have dual-primary endpoints of overall survival and progression-free survival. Updated data from the dose-escalation portion of ECHO-202, initial data from which was presented at SITC 2015 and drove the decision to initiate the Phase 3 trial, are expected to be presented in the second half of 2016. In addition, initial data from the ongoing Phase 2 dose-expansion cohorts investigating the safety and efficacy of epacadostat in combination with anti-PD-1 and anti-PD-L1 agents are anticipated to become available in the second half of 2016.

Driven by preclinical data presented at the AACR annual meeting in 2015, Incyte has launched two clinical platform studies to investigate a series of therapeutic doublet combinations on the tumor microenvironment. The PD-1 platform study will investigate the effects of adding either INCB39110 (JAK1) or INCB50465 (PI3Kδ) to pembrolizumab (PD-1). The JAK1 platform study will investigate all-oral doublets combining either INCB50465 (PI3Kδ) or epacadostat (IDO1) with INCB39110 (JAK1).

	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)
INCSHR1210 (PD-1, licensed from Hengrui)	Solid tumors	Phase 1/2 dose-escalation
INCAGN1876 (GITR, co-developed with Agenus)	Solid tumors	Phase 1/2 expected to initiate in the first half of 2016
INCAGN1949 (OX40, co-developed with Agenus)	Solid tumors	Phase 1/2 expected to initiate in the second half of 2016
PD-1 platform study	Solid tumors	Phase 1/2, pembrolizumab (PD-1) in combination with INCB39110 (JAK1) or INCB50465 (PI3Kδ)
JAK1 platform study	Solid tumors	Phase 1/2, INCB39110 (JAK1) in combination with epacadostat (IDO1) or INCB50465 (PI3Kδ)

Non Oncology

During the first quarter of 2016, Eli Lilly and Company began a series of global submissions seeking regulatory approval for baricitinib, a JAK1 / JAK2 inhibitor licensed by Incyte to Lilly. The submissions of the New Drug Application (NDA) and the Marketing Authorization Application (MAA) to the U.S. Food and Drug Administration and the European Medicines Agency, respectively, generated milestone payments from Lilly to Incyte. Incyte is eligible to earn further regulatory milestones and, if baricitinib is approved, will also become eligible for commercial milestones as well as royalties on global net sales. Baricitinib is also in Phase 2 trials for the treatment of atopic dermatitis and systemic lupus erythematosus.

Incyte recently announced an agreement with Lilly enabling Incyte to develop and commercialize ruxolitinib in the U.S. for the treatment of GVHD, and an agreement granting Novartis exclusive research, development and commercialization rights for ruxolitinib in GVHD ex-U.S. Incyte intends to initiate a U.S. registration program for ruxolitinib in GVHD in the second half of 2016. A proof-of-concept trial of INCB39110, a selective JAK1 inhibitor, in patients with GVHD is already underway.

	Indication	Status Update
Baricitinib (JAK1/JAK2, licensed to Lilly)	Rheumatoid arthritis	NDA & MAA submitted
	Psoriasis	Phase 2 studies completed
	Atopic dermatitis, systemic lupus erythematosus	Phase 2
Ruxolitinib (JAK1/JAK2)	Graft versus host disease	Phase 3 to begin in the second half of 2016
INCB39110 (JAK1)	Graft versus host disease	Phase 1/2
Topical ruxolitinib (JAK1/JAK2)	Alopecia areata	Phase 2

Conference Call and Webcast Information

Incyte will hold its 2016 first-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, 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 in the Investors section under “Events and Presentations”.

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.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

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.

Full Prescribing Information, including a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

About Iclusig® (ponatinib) tablets

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig was designed using ARIAD's computational and structure-based drug-design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

Iclusig is approved in the U.S., EU, Australia, Switzerland, Israel and Canada.

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Click here to view the Iclusig EU Summary of Medicinal Product Characteristics. Click here to view the EU Dear Healthcare Provider Letter (PDF).

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 revised financial guidance for 2016 and the expectations underlying such guidance, including guidance relating to the effect of the planned transactions with ARIAD; whether and when the planned acquisition of ARIAD's European operations and of the rights for Iclusig will close; whether and when this planned acquisition will effectively advance Incyte's European organization, maximize any future European product launches or be accretive to Incyte's earnings; whether and when any of Incyte's product candidates will be approved in Europe; 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; plans and expectations regarding the Company's product pipeline and strategy - including timelines for advancing its drug candidates through clinical trials, including enrollment and commencement, timelines for regulatory submissions and timelines for releasing trial data, and whether any specific program will be successful - including, without limitation, with respect to its selective JAK1 inhibitor, IDO1 inhibitor (epacadostat), FGFR inhibitor, BRD inhibitor, GITR, OX40, LSD1, PI3K-delta, c-Met, PD-1, PIM, GVHD and topical ruxolitinib 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; market competition; further research and development; sales, marketing and distribution requirements; clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; closing the planned acquisition of ARIAD's European operations; 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; the Company's dependence on its relationships with its collaboration partners; greater than expected expenses; expenses relating to litigation or strategic activities; our ability to obtain additional capital when needed; obtaining and maintaining effective patent coverage for the Company's 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-K for the year ended December 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 March 31,	
	2016	**2015**
Revenues:		
Product revenues, net	$183,267	$115,330
Product royalty revenues	21,903	15,673
Contract revenues	58,214	28,214
Other revenues	80	58
Total revenues	263,464	159,275
Costs and expenses:		
Cost of product revenues	6,005	2,974
Research and development	156,824	118,365
Selling, general and administrative	64,596	44,871
Total costs and expenses	227,425	166,210
Income (loss) from operations	36,039	(6,935)
Interest and other income, net	1,492	1,630

Interest expense	(10,134)	(12,687)
Unrealized loss on long term investment	(2,950)	-
Income (loss) before provision for income taxes	24,447	(17,992)
Provision for income taxes	400	367
Net income (loss)	$ 24,047	$(18,359)
Net income (loss) per share:		
Basic	$ 0.13	$ (0.11)
Diluted	$ 0.12	$ (0.11)
Shares used in computing net income (loss) per share:		
Basic	187,184	172,070
Diluted	192,625	172,070

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

	March 31, 2016	December 31, 2015
ASSETS		
Cash, cash equivalents and marketable securities	$ 810,669	$ 707,783
Restricted cash and investments	14,383	14,493
Accounts receivable	101,280	114,450
Property and equipment, net	92,622	86,006
Inventory	18,586	19,338
Prepaid expenses and other assets	34,104	30,122
Long term investment	32,298	35,248
Total assets	$1,103,942	$ 1,007,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 239,255	$ 203,880
Deferred revenue—collaborative agreements	9,297	12,512
Convertible senior notes	627,642	619,893
Stockholders' equity	227,748	171,155
Total liabilities and stockholders' equity	$1,103,942	$ 1,007,440

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