Incyte Reports 2016 Fourth-Quarter and Year-End Financial Results, Provides 2017 Financial Guidance and Updates on Key Clinical Programs

February 14, 2017

- *$238 million of 2016 fourth-quarter net product revenues from Jakafi® (ruxolitinib), representing 30 percent growth over the same period last year and $853 million of 2016 full-year net product revenues from Jakafi, representing 42 percent growth over last year*
- *Multiple pivotal programs expected to commence this year, including the combination of epacadostat and pembrolizumab in four additional solid tumor indications*
- *Expanding early-stage R&D portfolio, including the FGFR4 inhibitor program as well as recent collaborations in the fields of bispecific antibodies and arginase inhibition*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 14, 2017-- Incyte Corporation (Nasdaq:INCY) today reports 2016 fourth-quarter and year-end financial results, highlighting strong revenue growth driven by increased sales of Jakafi® (ruxolitinib) in the U.S. and Iclusig® (ponatinib) in Europe, and royalties from ex-U.S. sales of Jakavi® (ruxolitinib) by Novartis. Additionally, Incyte is providing financial guidance for 2017.

"We have had a very productive year at Incyte, during which we expanded our geographic footprint to include Europe and further advanced our clinical portfolio, including the recently announced expansion of the epacadostat development program," stated Hervé Hoppenot, Incyte's Chief Executive Officer. "Having now surpassed $1 billion in total annual revenue for the first time, we believe we are in a strong position to execute on our discovery and development objectives and build a global biopharmaceutical company bringing medicines to patients in need."

Baricitinib, a potential new oral treatment for patients with rheumatoid arthritis (RA) licensed to Eli Lilly and Company (Lilly), is now approved in Europe as Olumiant® and is under regulatory review globally. The European approval of Olumiant triggers a $65 million payment to Incyte from Lilly, and Incyte is eligible to receive additional potential milestone payments, as well as royalties on sales of Olumiant. Incyte has recently opted into co-development of multiple new indications for baricitinib, including psoriatic arthritis, in which Lilly is expected to begin a Phase 3 trial in 2017.

Incyte continues to expand its development portfolio—the Company anticipates the initiation of new pivotal trials in at least six indications from its broad late-stage portfolio during 2017 and is conducting four Phase 2 trials which, if successful, could also potentially act as registration-enabling studies. Two recent strategic collaborations have added to Incyte's early-stage R&D programs—the alliance with Merus provides access to bispecific drug discovery and the licensing agreement with Calithera adds INCB01158, a first-in-class oral arginase inhibitor, to Incyte's immuno-oncology development portfolio.

Portfolio Update

Cancer – Targeted Therapies

The pivotal program investigating ruxolitinib as a treatment for patients with graft-versus-host disease (GVHD) has begun. REACH1, the pivotal Phase 2 trial in patients with steroid-refractory acute GVHD, enrolled its first patient in December 2016; the REACH2 and REACH3 randomized Phase 3 trials in steroid-refractory acute and steroid-refractory chronic GVHD, respectively, are expected to begin in 2017 in collaboration with Novartis.

A pivotal program of ruxolitinib as a treatment for patients with essential thrombocythemia is also expected to begin in 2017.

Itacitinib (formerly INCB39110), Incyte's selective JAK1 inhibitor, is anticipated to enter a global pivotal development program for the treatment of patients with treatment-naïve acute GVHD during 2017.

In January 2017, Incyte disclosed its FGFR4 inhibitor discovery program, the lead molecule from which, INCB62079, is expected to enter proof-of-concept clinical trials during 2017.

	Indication	Status Update
Ruxolitinib (JAK1/JAK2)	Steroid-refractory acute GVHD	Pivotal (REACH1) trial underway; Phase 3 (REACH2) trial expected to begin in 2017
Ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD	Phase 3 (REACH3) trial expected to begin in 2017
Ruxolitinib (JAK1/JAK2)	Essential thrombocythemia	Pivotal program expected to begin in 2017
Itacitinib (JAK1)	Treatment-naïve acute GVHD	Pivotal program expected to begin in 2017
Itacitinib (JAK1)	Non-small cell lung cancer	Phase 1/2 in combination with osimertinib (EGFR)
INCB52793 (JAK1)	Advanced malignancies	Phase 1/2 dose-escalation
INCB50465 (PI3Kδ)	Diffuse large B cell lymphoma	Phase 2 (CITADEL-202) expected to begin in first half of 2017

INCB54828 (FGFR1/2/3)	Bladder cancer, cholangiocarcinoma; 8p11 MPNs	Phase 2
INCB54329 (BRD)	Advanced malignancies	Phase 1/2 dose-escalation
INCB57643 (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
INCB62079 (FGFR4)	Hepatocellular carcinoma	Phase 1/2 dose-escalation expected to begin in 2017

Cancer – Immune Therapies

In January 2017, Incyte and Merck announced the decision to expand the clinical development program investigating epacadostat with pembrolizumab, and plan to initiate Phase 3 trials of the combination in four additional tumors beyond melanoma: non-small cell lung cancer, renal cell carcinoma, bladder cancer and squamous cell carcinoma of the head and neck. These Phase 3 trials are expected to begin in 2017.

In January 2017, Incyte announced that it licensed worldwide rights from Calithera Biosciences to develop and commercialize INCB01158, a first-in-class, oral arginase inhibitor in hematology and oncology indications.

In February 2017, Incyte and Agenus announced an amended agreement, converting the ongoing GITR and OX40 antibody programs from co-funded development and profit-sharing arrangements to royalty-bearing programs, with Incyte now responsible for global development and commercialization.

	Indication	**Status Update**
Epacadostat (IDO1)	Unresectable or metastatic melanoma	Phase 3 (ECHO-301) in combination with pembrolizumab (PD-1)
	NSCLC, renal, bladder and head & neck cancer	Phase 3 in combination with pembrolizumab (PD-1) expected to begin in 2017
	Multiple tumor types	Phase 2 (ECHO-202) expansion cohorts in combination with pembrolizumab (PD-1)
	Multiple tumor types	Phase 2 (ECHO-204) expansion cohorts in combination with nivolumab (PD-1)
	Multiple tumor types	Phase 2 (ECHO-203) expansion cohorts in combination with durvalumab (PD-L1)
	NSCLC, bladder cancer	Phase 1/2 (ECHO-110) dose-escalation in combination with atezolizumab (PD-L1)
INCB01158 (ARG, co-developed with Calithera)	Solid tumors	Phase 1/2 dose-escalation
INCSHR1210 (PD-1, licensed from Hengrui)	Solid tumors	Phase 1/2 dose-escalation completed; enrollment suspended
INCAGN1876 (GITR)	Solid tumors	Phase 1/2 dose-escalation
INCAGN1949 (OX40)	Solid tumors	Phase 1/2 dose-escalation
PD-1 platform study	Solid tumors	Phase 1/2, pembrolizumab (PD-1) in combination with itacitinib (JAK1) or INCB50465 (PI3Kδ)
JAK1 platform study	Solid tumors	Phase 1/2, itacitinib (JAK1) in combination with epacadostat (IDO1) or INCB50465 (PI3Kδ)

Non-oncology

A Phase 2 trial of topical ruxolitinib for the treatment of patients with atopic dermatitis has recently been initiated, and a Phase 2 trial in patients with vitiligo is expected to begin during 2017.

	Indication	**Status Update**
Topical ruxolitinib (JAK1/JAK2)	Alopecia areata, atopic dermatitis	Phase 2
	Vitiligo	Phase 2 expected to begin in 2017

Partnered

In February 2017, the European Commission approved baricitinib – which will be marketed as Olumiant – for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs). In January 2017, the FDA extended the review period for the new drug application (NDA) for baricitinib by three months to allow time to review additional data analyses submitted by Lilly.

Lilly has announced its intention to initiate a Phase 3 program investigating baricitinib as a treatment for patients with psoriatic arthritis during 2017,

and Incyte has opted into co-development in this indication. Incyte has also opted into co-development in axial spondyloarthritis and atopic dermatitis, should Lilly decide to progress into a pivotal program in these indications.

Novartis anticipates submitting an NDA for capmatinib, Incyte's potent and selective c-MET inhibitor, in 2018.

	Indication	Status Update
Baricitinib (JAK1/JAK2, licensed to Lilly)	Rheumatoid arthritis	Approved in Europe; FDA review extended by three months
	Psoriatic arthritis	Phase 3 expected to begin in 2017
	Atopic dermatitis, systemic lupus erythematosus	Phase 2
Capmatinib (c-MET, licensed to Novartis)	Non-small cell lung cancer, liver cancer	Phase 2 in EGFR wild-type ALK negative NSCLC patients with c-MET amplification and mutation

2016 Fourth-Quarter and Full-Year Financial Results

Revenues For the quarter ended December 31, 2016, net product revenues of Jakafi were $238 million as compared to $182 million for the same period in 2015, representing 30 percent growth. For the full year ended December 31, 2016, net product revenues of Jakafi were $853 million as compared to $601 million for the same period in 2015, representing 42 percent growth.

For the quarter and seven month period ended December 31, 2016, net product revenues of Iclusig were $13 million and $30 million, respectively[1].

For the quarter and full year ended December 31, 2016, product royalties from sales of Jakavi outside of the United States received from Novartis were $33 million and $111 million, respectively, as compared to $24 million and $75 million, respectively, for the same periods in 2015.

For the quarter and full year ended December 31, 2016, contract revenues were $43 million and $113 million, respectively, as compared to $38 million and $78 million, respectively, for the same periods in 2015. The increase in contract revenues for the full year ended December 31, 2016 relates to milestone payments earned.

For the quarter ended December 31, 2016, total revenues were $326 million as compared to $244 million for the same period in 2015. For the full year ended December 31, 2016, total revenues were $1,106 million as compared to $754 million for the same period in 2015.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended December 31,		%	Twelve Months Ended December 31,		%
	2016	2015	Change	2016	2015	Change
Revenues:						
Jakafi net product revenue	$ 237,531	$ 182,021	30%	$ 852,816	$ 601,015	42%
Iclusig net product revenue	12,867	-	-	29,588	-	-
Product royalty revenues	33,225	23,646	41%	110,711	74,821	48%
Contract revenues	42,869	38,214	-	112,512	77,857	-
Other revenues	6	-	-	92	58	-
Total revenues	$ 326,498	$ 243,881	34%	$ 1,105,719	$ 753,751	47%

Research and development expenses Research and development expenses for the quarter and full year ended December 31, 2016 were $162 million and $582 million, respectively, as compared to $117 million and $480 million, respectively, for the same periods in 2015. Included in research and development expenses for the quarter and full year ended December 31, 2016 were non-cash expenses related to equity awards to our employees of $17 million and $60 million, respectively. The increase in research and development expenses for the full year ended December 31, 2016 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 and full year ended December 31, 2016 were $96 million and $303 million, respectively, as compared to $52 million and $197 million, respectively, for the same periods in 2015. Included in selling, general and administrative expenses for the quarter and full year ended December 31, 2016 were non-cash expenses related to equity awards to our employees of $10 million and $36 million, respectively. Increased selling, general and administrative expenses are driven primarily by additional costs related to the commercialization of Jakafi and the geographic expansion in Europe.

Change in fair value of acquisition-related contingent consideration The change in fair value of acquisition-related contingent consideration of $7 million and $17 million for the quarter and seven month period ended December 31, 2016 represents the fair market value adjustments of the Company's contingent liability related to the acquisition of the European business of ARIAD Pharmaceuticals, Inc.

Unrealized loss on long term investment Unrealized loss on long term investment for the quarter and full year ended December 31, 2016 were of $24 million and $3 million, respectively, as compared to $0 million and $5 million, respectively, for the same periods in 2015. The unrealized loss on long term investment represents the fair market value adjustments of the Company's investment in Agenus.

Net income Net income for the quarter ended December 31, 2016 was $9 million, or $0.05 per basic and diluted share, as compared to net income of

$55 million, or $0.30 per basic and $0.29 per diluted share for the same period in 2015. Net income for the full year ended December 31, 2016 was $104 million, or $0.55 per basic and $0.54 per diluted share, as compared to net income of $7 million, or $0.04 per basic and $0.03 per diluted share for the same period in 2015.

Cash, cash equivalents and marketable securities position As of December 31, 2016, cash, cash equivalents and marketable securities totaled $809 million, as compared to $708 million as of December 31, 2015.

2017 Financial Guidance

The Company has provided full year 2017 financial guidance, as detailed below.

	Guidance
Jakafi net product revenues	$1,020-$1,070 million
Iclusig net product revenues	$60-$65 million
Research and development expenses: ongoing	$785-$835 million
Research and development expenses: anticipated one-time items*	$205 million
Selling, general and administrative expenses	$340-$360 million
Change in fair value of acquisition-related contingent consideration	$30-$35 million

* One-time items related to the amended Agenus collaboration, and the Merus and Calithera collaborations

Conference Call and Webcast Information

Incyte will hold its 2016 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, 13653254.

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, 13653254.

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.

About Iclusig® (ponatinib) tablets

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.

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.

Incyte has an exclusive license from ARIAD Pharmaceuticals, Inc to develop and commercialize Iclusig in the European Union and 22 other countries, including Switzerland, Norway, Turkey, Israel and Russia.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the Company’s financial guidance for 2017 and the expectations underlying such guidance; whether and when the Company will receive potential milestone payments or royalty payments from Lilly with respect to baricitinib and whether baricitinib will be approved in the U.S.; and 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), whether certain trials will serve as the basis for registration, timelines for regulatory submissions and timelines for releasing trial data, and whether any specific program will be successful - and plans and expectations regarding development activities of the Company’s collaboration partners.

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 our products; the acceptance of our products in the marketplace; market competition; further research and development; sales, marketing and distribution requirements; clinical trials, including pivotal 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; 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-Q for the quarter ended September 30, 2016. The Company disclaims any intent or obligation to update these forward-looking statements.

[1] In June 2016, Incyte obtained an exclusive license from ARIAD to develop and commercialize Iclusig in Europe and other select ex-U.S. countries.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Product revenues, net	$250,398	$182,021	$ 882,404	$601,015
Product royalty revenues	33,225	23,646	110,711	74,821
Contract revenues	42,869	38,214	112,512	77,857
Other revenues	6	-	92	58
Total revenues	326,498	243,881	1,105,719	753,751
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	19,610	9,704	58,187	26,972
Research and development	161,585	116,630	581,861	479,514
Selling, general and administrative	96,085	52,467	303,251	196,614
Change in fair value of acquisition-related contingent consideration	7,139	-	17,422	-
Total costs and expenses	284,419	178,801	960,721	703,100
Income from operations	42,079	65,080	144,998	50,651
Interest and other income, net	594	1,289	4,412	7,089
Interest expense	(9,470)	(10,213)	(38,745)	(45,603)
Unrealized loss on long term investment	(23,758)	(466)	(3,261)	(4,581)
Income before provision for income taxes	9,445	55,690	107,404	7,556
Provision for income taxes	572	512	3,182	1,025
Net income	$ 8,873	$ 55,178	$ 104,222	$ 6,531
Net income per share:				
Basic	$ 0.05	$ 0.30	$ 0.55	$ 0.04
Diluted	$ 0.05	$ 0.29	$ 0.54	$ 0.03
Shares used in computing net income per share:				
Basic	188,598	186,269	187,873	179,601
Diluted	195,187	193,367	194,125	187,302

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

	December 31, 2016	**December 31, 2015**
ASSETS		
Cash, cash equivalents and marketable securities	$ 808,546	$ 707,783
Restricted cash and investments	902	14,493

Accounts receivable	148,758	114,450
Property and equipment, net	167,679	86,006
Inventory	19,299	19,338
Prepaid expenses and other assets	35,396	30,122
Long term investment	31,987	35,248
Other intangible assets, net	258,437	-
In-process research and development	12,000	-
Goodwill	155,593	-
Total assets	$ 1,638,597	$ 1,007,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 266,649	$ 203,880
Deferred revenue—collaborative agreements	-	12,512
Convertible senior notes	651,481	619,893
Acquisition-related contingent consideration	301,000	-
Stockholders' equity	419,467	171,155
Total liabilities and stockholders' equity	$ 1,638,597	$ 1,007,440

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