Incyte Reports 2016 Third-Quarter Financial Results and Updates Key Clinical Programs

November 1, 2016

- *$224 million of 2016 third-quarter net product revenues from Jakafi® (ruxolitinib), representing 39 percent growth over the same period last year*
- *Jakafi included as a recommended treatment for patients with myelofibrosis in the NCCN® Guidelines for myeloproliferative neoplasms (MPNs)*
- *Updated Phase 1 data from ECHO-202 reinforced durability of anti-tumor response in patients with advanced or metastatic melanoma treated with epacadostat plus Keytruda® (pembrolizumab)*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 1, 2016-- Incyte Corporation (Nasdaq: INCY) today reports 2016 third-quarter financial results, including strong revenue growth driven by increased sales of Jakafi® (ruxolitinib) in the U.S., Iclusig® (ponatinib) in Europe and royalties from ex-U.S. sales of Jakavi® (ruxolitinib) by Novartis. In September, Jakafi was included as a recommended treatment for appropriate patients with myelofibrosis in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology, underscoring the important and long-term clinical benefits seen in patients treated with Jakafi.

The Company also highlighted progress being made across its clinical portfolio. Within the targeted therapies segment, two Phase 2 trials of INCB54828, a selective FGFR inhibitor, are now open for recruitment in bladder cancer and cholangiocarcinoma, respectively. In immuno-oncology, updated Phase 1 data from ECHO-202 were recently presented at the ESMO Congress, supporting the therapeutic profile of epacadostat plus pembrolizumab for the first-line treatment of patients with advanced or metastatic melanoma.

“Incyte continues to deliver dynamic sales growth from Jakafi in the U.S. and now from Iclusig in Europe. With a potential additional future source of revenue from baricitinib, we are able to make significant investments in opportunities across our broad and diverse clinical portfolio,” stated Hervé Hoppenot, Incyte’s Chief Executive Officer. “Our commercial footprint has expanded to include Europe in addition to the U.S., and as our portfolio matures, we are in an excellent position to build Incyte into a world-class biopharmaceutical organization.”

2016 Third-Quarter Financial Results

Revenues For the quarter ended September 30, 2016, net product revenues of Jakafi were $224 million as compared to $161 million for the same period in 2015, representing 39 percent growth. For the nine months ended September 30, 2016, net product revenues of Jakafi were $615 million as compared to $419 million for the same period in 2015, representing 47 percent growth. For the quarter and four month period ended September 30, 2016, net product revenues of Iclusig were $13 million and $17 million, respectively[1]. For the quarter and nine months ended September 30, 2016, product royalties from sales of Jakavi outside of the United States received from Novartis were $30 million and $77 million, respectively, as compared to $18 million and $51 million, respectively, for the same periods in 2015. For the quarter and nine months ended September 30, 2016, contract revenues were $3 million and $70 million, respectively, as compared to $8 million and $40 million, respectively, for the same periods in 2015. The increase in contract revenues for the nine months ended September 30, 2016 relates to milestone payments earned. For the quarter ended September 30, 2016, total revenues were $269 million as compared to $188 million for the same period in 2015. For the nine months ended September 30, 2016, total revenues were $779 million as compared to $510 million for the same period in 2015.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2016	2015	Change	2016	2015	Change
Revenues:						
Jakafi net product revenue	$ 223,892	$ 161,259	39%	$ 615,285	$ 418,994	47%
Iclusig net product revenue	12,731	-	-	16,721	-	-
Product royalty revenues	29,626	18,138	63%	77,486	51,175	51%
Contract revenues	3,214	8,214	-	69,643	39,643	-
Other revenues	6	-	-	86	58	-
Total revenues	$ 269,469	$ 187,611	44%	$ 779,221	$ 509,870	53%

In October 2016, the Company was notified by Novartis that a $40 million milestone payment obligation to Incyte related to reimbursement of Jakavi in Europe for polycythemia vera had been triggered. The Company expects to record this payment as contract revenue during the fourth quarter of 2016.

Research and development expenses Research and development expenses for the quarter and nine months ended September 30, 2016 were $143

million and $420 million, respectively, as compared to $132 million and $363 million, respectively, for the same periods in 2015. Included in research and development expenses for the quarter and nine months ended September 30, 2016 were non-cash expenses related to equity awards to our employees of $16 million and $43 million, respectively. The increase in research and development expenses for the nine months ended September 30, 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 nine months ended September 30, 2016 were $76 million and $207 million, respectively, as compared to $48 million and $144 million, respectively, for the same periods in 2015. Included in selling, general and administrative expenses for the quarter and nine months ended September 30, 2016 were non-cash expenses related to equity awards to our employees of $10 million and $26 million, respectively. Increased selling, general and administrative expenses are driven primarily by additional costs related to the commercialization of Jakafi.

Change in fair value of acquisition-related contingent consideration The change in fair value of acquisition-related contingent consideration of $8 million and $10 million for the quarter and nine months ended September 30, 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 gain on long term investment Unrealized gain on long term investment of $24 million and $20 million for the quarter and nine months ended September 30, 2016 represents the fair market value adjustments of the Company's investment in Agenus.

Net income / (loss) Net income for the quarter ended September 30, 2016 was $37 million, or $0.20 per basic and $0.19 per diluted share, as compared to net loss of $40 million, or $0.22 per basic and diluted share for the same period in 2015. Net income for the nine months ended September 30, 2016 was $95 million, or $0.51 per basic and $0.49 per diluted share, as compared to net loss of $49 million, or $0.27 per basic and diluted share for the same period in 2015.

Cash, cash equivalents and marketable securities position As of September 30, 2016, cash, cash equivalents and marketable securities totaled $717 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.

	Current	Previous
Jakafi net product revenues	$850-$855 million	$825-$835 million
Iclusig net product revenues	$25-$30 million	Unchanged
Research and development expenses	$570-$580 million	$620-$630 million
Selling, general and administrative expenses	$285-$310 million	Unchanged
Change in fair value of acquisition-related contingent consideration	$17 million	Unchanged

Portfolio Update

Cancer – Targeted Therapies

Two trials of INCB54828, a selective FGFR inhibitor, in patients with bladder cancer and cholangiocarcinoma, respectively, harboring FGFR alterations are now open for recruitment.

Incyte has two BRD inhibitors in clinical trials, INCB54329 and INCB57643. Having two distinct compounds allows the Company to evaluate the clinical safety and tolerability of different pharmacokinetic and pharmacodynamic profiles within a therapeutic class.

	Indication	Status Update
Ruxolitinib (JAK1/JAK2)	Graft versus host disease	Pivotal program expected to begin in the fourth quarter of 2016
INCB39110 (JAK1)	Graft versus host disease	Phase 1/2 fully recruited, data expected before the end of 2016
INCB39110 (JAK1)	Lung cancer	Phase 1/2 in combination with osimertinib (EGFR) expected to begin in the fourth quarter of 2016
INCB52793 (JAK1)	Advanced malignancies	Phase 1/2 dose-escalation
INCB50465 (PI3Kδ)	B-cell malignancies	Phase 1/2 as monotherapy and in combination with INCB39110 (JAK1)
INCB54828 (FGFR)	Bladder cancer, cholangiocarcinoma	Phase 2 open for recruitment
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

Cancer – Immune Therapies

Updated Phase 1 data from the ECHO-202 trial of epacadostat plus pembrolizumab was recently presented at ESMO, showing durable responses in patients with advanced or metastatic melanoma, and a well-tolerated safety profile. These data reinforce Incyte's confidence in the decision to move this immunotherapy combination into the ongoing ECHO-301 Phase 3 trial for the first-line treatment of patients with advanced or metastatic

melanoma.

	Indication	Status Update
Epacadostat	First line, advanced melanoma	Phase 3 (ECHO-301) in combination with pembrolizumab (PD-1)
	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)
	Non-small cell lung cancer, bladder cancer	Phase 1/2 (ECHO-110) dose-escalation in combination with atezolizumab (PD-L1)
INCSHR1210 (PD-1, licensed from Hengrui)	Solid tumors	Phase 1/2 dose-escalation completed; enrollment suspended
INCAGN1876 (GITR, co-developed with Agenus)	Solid tumors	Phase 1/2 dose-escalation
INCAGN1949 (OX40, co-developed with Agenus)	Solid tumors	Phase 1/2 dose-escalation expected to begin in the fourth quarter 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

Data from Incyte's Phase 2 trial of topical ruxolitinib for the treatment of patients with alopecia areata have been accepted for presentation at the National Alopecia Areata Foundation's Alopecia Areata Research Summit on November 14, 2016.

	Indication	Status Update
Topical ruxolitinib (JAK1/JAK2)	Alopecia areata	Phase 2

Partnered

Baricitinib, a JAK1/JAK2 inhibitor licensed to Lilly, is under global regulatory review for the treatment of patients with rheumatoid arthritis. If approved, Incyte will become eligible to earn regulatory and commercial milestones as well as royalties on global net sales.

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	NDA & MAA submitted
	Atopic dermatitis, systemic lupus erythematosus	Phase 2
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

Conference Call and Webcast Information

Incyte will hold its 2016 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, 13647886.

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, 13647886.

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 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; whether and when the Company will receive potential 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 GVHD, ruxolitinib, selective JAK1 inhibitor, IDO1 inhibitor (epacadostat), FGFR inhibitor, OX40 and c-Met programs; and whether Novartis will submit an NDA for capmatinib in 2018.

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 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 June 30, 2016. The Company disclaims any intent or obligation to update these forward-looking statements.

[1] In June 2016 we 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product revenues, net	$236,623	$ 161,259	$632,006	$418,994
Product royalty revenues	29,626	18,138	77,486	51,175
Contract revenues	3,214	8,214	69,643	39,643
Other revenues	6	-	86	58
Total revenues	269,469	187,611	779,221	509,870
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	20,205	8,040	38,577	17,268
Research and development	143,184	132,073	420,276	362,882
Selling, general and administrative	75,776	47,599	207,166	144,147
Change in fair value of acquisition-related contingent consideration	8,012	-	10,283	-
Total costs and expenses	247,177	187,712	676,302	524,297

Income (loss) from operations	22,292	(101)	102,919	(14,427)
Interest and other income, net	1,188	3,026	3,818	5,800
Interest expense	(9,479)	(11,209)	(29,275	(35,390)
Unrealized gain (loss) on long term investment	24,301	(31,289)	20,497	(4,115)
Income (loss) before provision for income taxes	38,302	(39,573)	97,959	(48,132)
Provision for income taxes	1,425	9	2,610	513
Net income (loss)	$ 36,877	$ (39,582	$ 95,349	$(48,645))
Net income (loss) per share:				
Basic	$ 0.20	$ (0.22)	$ 0.51	$ (0.27)
Diluted	$ 0.19	$ (0.22)	$ 0.49	$ (0.27)
Shares used in computing net income (loss) per share:				
Basic	188,029	181,387	187,632	177,378
Diluted	194,265	181,387	193,754	177,378

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

	September 30, 2016	December 31, 2015
ASSETS		
Cash, cash equivalents and marketable securities	$ 716,585	$ 707,783
Restricted cash and investments	949	14,493
Accounts receivable	131,523	114,450
Property and equipment, net	151,942	86,006
Inventory	18,907	19,338
Prepaid expenses and other assets	37,021	30,122
Long term investment	55,745	35,248
Other intangible assets, net	263,821	-
In-process research and development	12,000	-
Goodwill	155,702	-
Total assets	$ 1,544,195	$ 1,007,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 229,907	$ 203,880
Deferred revenue—collaborative agreements	2,868	12,512
Convertible senior notes	643,434	619,893
Acquisition-related contingent consideration	298,000	-
Stockholders' equity	369,986	171,155
Total liabilities and stockholders' equity	$ 1,544,195	$ 1,007,440

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