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

August 9, 2016

- *$208 million of 2016 second-quarter net product revenues from Jakafi® (ruxolitinib), representing 46 percent growth over the same period last year*
- *ECHO-301, the first Phase 3 trial evaluating epacadostat, now underway in combination with pembrolizumab as first-line treatment of patients with advanced or metastatic melanoma*
- *New Phase 3 clinical data from COMFORT-I in myelofibrosis and RESPONSE-2 in polycythemia vera reinforce the leadership position of Jakafi in the treatment of patients with these myeloproliferative neoplasms (MPNs)*
- *Ruxolitinib granted Breakthrough Therapy Designation by the FDA for the treatment of patients with acute graft-versus-host disease (GVHD)*

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

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

The long-term clinical profile of Jakafi was reinforced by the presentation of five-year overall survival data from the COMFORT-I trial in patients with myelofibrosis at the recent American Society of Clinical Oncology (ASCO) meeting and the successful results from the RESPONSE-2 Phase 3 trial in patients with uncontrolled polycythemia vera highlighted at the European Hematology Association (EHA) congress. Additionally, ruxolitinib has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with acute GVHD.

Baricitinib, currently under global regulatory review for the treatment of patients with rheumatoid arthritis, may provide Incyte with a further valuable source of revenue, given the potential for milestones and royalties under the Company's license agreement with Eli Lilly and Company. The first regulatory approval for baricitinib is anticipated in the first quarter of next year.

Incyte has a growing international footprint, which was accelerated by the recent ARIAD transaction in Europe, and now has a development, medical and commercial organization in Europe to complement its fully-integrated U.S. business. The expanded European team is fully operational, and will continue to grow the Iclusig® (ponatinib) brand as well as contribute to the clinical development of Incyte's portfolio of 14 product candidates.

Within the R&D group, and during the second quarter of 2016, Incyte initiated the first pivotal Phase 3 trial of epacadostat, added a new clinical program with the initiation of a first-in-man trial of INCAGN1876, an anti-GITR agonist antibody, and signed a drug discovery alliance with the Moffitt Cancer Center – collectively illustrating the depth and breadth of Incyte's discovery and development programs.

"Incyte is in an excellent position both financially and operationally as we enter the second half of the year," stated Hervé Hoppenot, Incyte's Chief Executive Officer. "Jakafi continues to grow rapidly in the U.S., and we have successfully incorporated our expanded European team. The recent initiation of the first Phase 3 trial of epacadostat was a significant milestone for Incyte, and we are preparing to launch the pivotal program for ruxolitinib in GVHD."

2016 Second-Quarter Financial Results

Revenues For the quarter ended June 30, 2016, net product revenues of Jakafi were $208 million as compared to $142 million for the same period in 2015, representing 46 percent growth. For the six months ended June 30, 2016, net product revenues of Jakafi were $391 million as compared to $258 million for the same period in 2015, representing 52 percent growth. For the quarter and six months ended June 30, 2016, net product revenues of Iclusig were $4 million. For the quarter and six months ended June 30, 2016, product royalties from sales of Jakavi outside of the United States received from Novartis were $26 million and $48 million, respectively, as compared to $17 million and $33 million, respectively, for the same periods in 2015. For the quarter and six months ended June 30, 2016, contract revenues were $8 million and $66 million, respectively, as compared to $3 million and $31 million, respectively, for the same periods in 2015. The increase in contract revenues relates to milestone payments earned. For the quarter ended June 30, 2016, total revenues were $246 million as compared to $163 million for the same period in 2015. For the six months ended June 30, 2016, total revenues were $510 million as compared to $322 million for the same period in 2015.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	% Change	2016	2015	% Change

Revenues:						
Jakafi net product revenue	$ 208,126	$ 142,406	46%	$ 391,393	$ 257,736	52%
Iclusig net product revenue	3,990	-	-	3,990	-	-
Product royalty revenues	25,958	17,364	49%	47,860	33,037	45%
Contract revenues	8,214	3,214	-	66,429	31,429	-
Other revenues	-	-	-	80	58	-
Total revenues	$ 246,288	$ 162,984	51%	$ 509,752	$ 322,260	58%

Research and development expenses Research and development expenses for the quarter and six months ended June 30, 2016 were $120 million and $277 million, respectively, as compared to $112 million and $231 million, respectively, for the same periods in 2015. Included in research and development expenses for the quarter and six months ended June 30, 2016 were non-cash expenses related to equity awards to our employees of $14 million and $27 million, respectively. The increase in research and development expenses for the six months ended June 30, 2016 was primarily due to the previously announced $35 million upfront payment to acquire the rights from Lilly to develop ruxolitinib for the treatment of patients with GVHD and the expansion of the Company's clinical portfolio.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter and six months ended June 30, 2016 were $67 million and $131 million, respectively, as compared to $52 million and $97 million, respectively, for the same periods in 2015. Included in selling, general and administrative expenses for the quarter and six months ended June 30, 2016 were non-cash expenses related to equity awards to our employees of $8 million and $16 million, respectively. 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 $1 million and $4 million for the quarter and six months ended June 30, 2016 represents the fair market value adjustments of the Company's investment in Agenus.

Net income / (loss) Net income for the quarter ended June 30, 2016 was $34 million, or $0.18 per basic and diluted share, as compared to net income of $9 million, or $0.05 per basic and diluted share for the same period in 2015. Net income for the six months ended June 30, 2016 was $58 million, or $0.31 per basic and $0.30 per diluted share, as compared to net loss of $9 million, or $0.05 per basic and diluted share for the same period in 2015.

Cash, cash equivalents and marketable securities position As of June 30, 2016, cash, cash equivalents and marketable securities totaled $629 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	$825-$835 million	$815-$830 million
Iclusig net product revenues	$25-$30 million	Unchanged
Research and development expenses	$620-$630 million	$635-$660 million
Selling, general and administrative expenses	$285-$310 million	Unchanged

Corporate Update

In June 2016, Jonathan Dickinson joined the Executive Management team as Senior Vice President and General Manager, Europe, leading the commercial and medical affairs functions for Incyte in Europe. He joined Incyte from ARIAD Pharmaceuticals (Europe) Sàrl where he held the position of General Manager, Europe. Prior to his tenure at ARIAD, Jonathan worked at Bristol-Myers Squibb as the European oncology brand lead and at Hoffmann-La Roche where he had assignments both in the U.S. and Switzerland.

Portfolio Update

Cancer – Targeted Therapies

In April 2016, Incyte 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 recently announced that the FDA has granted Breakthrough Therapy Designation for ruxolitinib in patients with acute GVHD.

A proof-of-concept trial of INCB39110, a selective JAK1 inhibitor, in patients with GVHD has completed recruitment and initial data is expected before the end of 2016.

In April 2016, 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.

A Phase 2 trial of INCB54828, a selective FGFR inhibitor, in patients with bladder cancer harboring FGFR pathway alterations is expected to start in the second half of 2016.

	Indication	**Status Update**
Ruxolitinib (JAK1/JAK2)	Graft versus host disease	Pivotal program expected to begin in the second half 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 initiate in the second half 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	Phase 2 expected to initiate in the second half of 2016
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

Cancer – Immune Therapies

The Phase 3 ECHO-301 study evaluating epacadostat in combination with the anti-PD-1 antibody, pembrolizumab, for the first-line treatment of patients with advanced or metastatic melanoma is now recruiting patients. The randomized, double-blind and placebo controlled trial, is planned to enroll 600 patients and to have dual-primary endpoints of progression-free survival and overall survival.

Updated data from the Phase 1 portion of ECHO-202, which was initially presented at SITC 2015 and drove the decision to initiate the Phase 3 trial, have been accepted for presentation at the European Society for Medical Oncology (ESMO) congress taking place in Copenhagen in October 2016.

In June 2016, the proof-of-concept trial of INCAGN1876, an anti-GITR agonist antibody being co-developed with Agenus, began dosing patients with solid tumors.

	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	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
INCAGN1876 (GITR, co-developed with Agenus)	Solid tumors	Phase 1/2 dose-escalation
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

In October 2015, Incyte initiated a Phase 2 trial of topical ruxolitinib for the treatment of alopecia areata. This study builds on published data showing the efficacy of oral JAK inhibitors, including ruxolitinib, in alopecia areata.

	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. Baricitinib is also in Phase 2 trials for the treatment of patients with atopic dermatitis and systemic lupus erythematosus.

In June 2016, safety and efficacy data from several Phase 1 and Phase 2 trials of capmatinib, Incyte's potent and selective c-MET inhibitor licensed to

Novartis, as single agent and in combination with gefitinib in patients with c-MET positive non-small cell lung cancer and liver cancer, were presented at ASCO. Novartis anticipates submitting an NDA for capmatinib 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 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, 13641107.

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, 13641107.

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; whether the Company’s expanded European team will grow the Iclusig brand or contribute to clinical development; 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 March 31, 2016. 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Product revenues, net	$ 212,116	$ 142,406	$ 395,383	$ 257,736
Product royalty revenues	25,958	17,364	47,860	33,037
Contract revenues	8,214	3,214	66,429	31,429
Other revenues	-	-	80	58
Total revenues	246,288	162,984	509,752	322,260
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	12,367	6,254	18,372	9,229
Research and development	120,269	112,445	277,092	230,809
Selling, general and administrative	66,792	51,679	131,390	96,548
Change in fair value of acquisition-related contingent consideration	2,271	-	2,271	-
Total costs and expenses	201,699	170,378	429,125	336,586
Income (loss) from operations	44,589	(7,394)	80,627	(14,326)
Interest and other income, net	1,137	1,144	2,630	2,773
Interest expense	(9,662)	(11,494)	(19,796)	(24,181)
Unrealized gain (loss) on long term investment	(854)	27,174	(3,804)	27,174
Income (loss) before provision for income taxes	35,210	9,430	59,657	(8,560)
Provision for income taxes	785	136	1,185	503
Net income (loss)	$ 34,425	$ 9,294	$ 58,472	$ (9,063)
Net income (loss) per share:				
Basic	$ 0.18	$ 0.05	$ 0.31	$ (0.05)
Diluted	$ 0.18	$ 0.05	$ 0.30	$ (0.05)
Shares used in computing net income (loss) per share:				
Basic	187,682	178,676	187,433	175,373
Diluted	193,015	186,493	192,820	175,373

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

	June 30, 2016	December 31, 2015
ASSETS		
Cash, cash equivalents and marketable securities	$ 629,191	$ 707,783
Restricted cash and investments	938	14,493
Accounts receivable	129,486	114,450
Property and equipment, net	138,513	86,006
Inventory	21,664	19,338
Prepaid expenses and other assets	29,809	30,122
Long term investment	31,444	35,248
Other intangible assets, net	269,205	-
In-process research and development	12,000	-
Goodwill	155,725	-
Total assets	$ 1,417,975	$ 1,007,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 185,338	$ 203,880
Deferred revenue—collaborative agreements	6,083	12,512

Convertible senior notes	635,491	619,893
Acquisition-related contingent consideration	294,000	-
Stockholders' equity	297,063	171,155
Total liabilities and stockholders' equity	$ 1,417,975	$ 1,007,440

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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