Incyte Reports 2017 Third-Quarter Financial Results and Updates on Key Clinical Programs

October 31, 2017

- *$304 million of 2017 third-quarter net product revenues from Jakafi® (ruxolitinib), representing 36 percent growth over the same period last year*
- *Progress across the portfolio as multiple candidates enter late-stage development trials*
- *Two recent collaborations further expand potential and scope of Incyte's combination immunotherapy development activities*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 31, 2017-- Incyte Corporation (Nasdaq: INCY) today reports 2017 third-quarter financial results, highlighting 38 percent year-on-year growth in product-related revenue, 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 and Olumiant® (baricitinib) by Lilly.

"We exit the third quarter of 2017 with excellent momentum across the whole business," stated Hervé Hoppenot, Incyte's Chief Executive Officer. "Jakafi and Iclusig continue to outperform our expectations, and we are now evaluating ten different indications across our five late-stage development candidates. We are also on track to initiate the next wave of pivotal trials planned for the epacadostat development program. We are striving to build Incyte into a world-class biopharmaceutical company, and we are very pleased to report another quarter of significant progress towards that goal."

Portfolio Update

Cancer – Targeted Therapies

The REACH1 pivotal trial studying ruxolitinib in patients with steroid-refractory acute graft-versus-host disease (GVHD) is on track to deliver results in the first half of 2018. If successful, Incyte anticipates submitting an sNDA seeking accelerated approval of ruxolitinib in this indication during 2018. Three additional pivotal trials are evaluating the role of JAK inhibition in GVHD (REACH2 and REACH3 with ruxolitinib, and GRAVITAS-301 with itacitinib).

The FIGHT and CITADEL programs evaluating INCB54828 (FGFR1/2/3) and INCB50465 (PI3Kδ), respectively, now include multiple different indications in potentially-pivotal trials.

	Indication	Status Update
Ruxolitinib (JAK1/JAK2)	Steroid-refractory acute GVHD	Pivotal Phase 2 (REACH1) and Phase 3 (REACH2)
Ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD	Phase 3 (REACH3)
Ruxolitinib (JAK1/JAK2)	Essential thrombocythemia	Pivotal Phase 2 (RESET-272) open for enrollment
Itacitinib (JAK1)	Treatment-naïve acute GVHD	Phase 3 (GRAVITAS-301)
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, follicular lymphoma, marginal zone lymphoma, mantle cell lymphoma	Phase II (CITADEL-202 initiated; CITADEL-203, CITADEL-204, CITADEL-205 all open for enrollment)
INCB54828 (FGFR1/2/3)	Bladder cancer, cholangiocarcinoma; 8p11 MPNs	Phase 2 (FIGHT-201, FIGHT-202, FIGHT-203)
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

Cancer – Immune Therapies

The pivotal Phase 3 ECHO-301 trial of epacadostat plus pembrolizumab in patients with unresectable or metastatic melanoma is now fully-recruited and data are expected in the first half of 2018.

In collaboration with Merck and Bristol-Myers Squibb, preparations for the next wave of eight pivotal Phase 3 trials of epacadostat plus PD-1

antagonists continue as planned. Initiation of these trials are expected before the end of 2017.

In October, Incyte and AstraZeneca announced an expanded clinical trial collaboration and the companies intend to initiate a Phase 3 trial of epacadostat in combination with AstraZeneca's PD-L1 antagonist durvalumab in patients with Stage III non-small cell lung cancer.

In October, Incyte and MacroGenics announced an exclusive global collaboration and license agreement for MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Under this agreement, Incyte will obtain exclusive worldwide rights for the development and commercialization of MGA012 in all indications.

	Indication	Status Update
Epacadostat (IDO1)	Unresectable or metastatic melanoma	Phase 3 (ECHO-301) in combination with pembrolizumab (PD-1)
Epacadostat (IDO1)	NSCLC, renal, bladder and head & neck cancer	Phase 3 in combination with pembrolizumab (PD-1) expected to begin in 2017
Epacadostat (IDO1)	NSCLC, head & neck cancer	Phase 3 in combination with nivolumab (PD-1) expected to begin in 2017
Epacadostat (IDO1)	NSCLC	Phase 3 in combination with durvalumab (PD-L1) expected to begin in H1 2018
Epacadostat (IDO1)	Multiple tumor types	Phase 2 (ECHO-202) expansion cohorts in combination with pembrolizumab (PD-1)
Epacadostat (IDO1)	Multiple tumor types	Phase 2 (ECHO-204) expansion cohorts in combination with nivolumab (PD-1)
Epacadostat (IDO1)	Multiple tumor types	Phase 2 (ECHO-203) expansion cohorts in combination with durvalumab (PD-L1)
INCB01158 (ARG)[1]	Solid tumors	Phase 1/2
INCSHR1210 (PD-1)[2]	Solid tumors	Phase 1/2; enrollment halted
INCAGN1876 (GITR)[3]	Solid tumors	Phase 1/2
INCAGN1949 (OX40)[3]	Solid tumors	Phase 1/2
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)

Notes:

1) INCB01158 co-developed with Calithera
2) INCSHR1210 licensed from Hengrui
3) INCAGN1876 & INCAGN1949 from discovery alliance with Agenus

Non-oncology

	Indication	Status Update
Topical ruxolitinib (JAK1/JAK2)	Atopic dermatitis, vitiligo	Phase 2

Partnered

In August, Lilly and Incyte announced that Lilly plans to resubmit the New Drug Application (NDA) for baricitinib to the U.S. Food & Drug Administration (FDA) before the end of January 2018. The companies anticipate the FDA will classify the application as a Class II resubmission, which would start a new six-month review cycle.

In September, Lilly and Incyte announced that baricitinib met the primary endpoint in a Phase 2 study in patients with moderate-to-severe atopic dermatitis.

Novartis has stated that it anticipates submitting an NDA for capmatinib, a potent and selective c-MET inhibitor licensed from Incyte, in 2018.

	Indication	Status Update
Baricitinib (JAK1/JAK2)[1]	Rheumatoid arthritis	Approved in Europe and Japan; CRL issued by FDA
Baricitinib (JAK1/JAK2)[1]	Psoriatic arthritis	Lilly expects the Phase 3 program to begin in 2018
Baricitinib (JAK1/JAK2)[1]	Atopic dermatitis	Lilly expects the Phase 3 program to begin in late 2017
Baricitinib (JAK1/JAK2)[1]	Systemic lupus erythematosus	Phase 2

Capmatinib (c-MET)[2]	Non-small cell lung cancer, liver cancer	Phase 2 in EGFR wild-type ALK negative NSCLC patients with c-MET amplification and mutation

Notes:

1) Baricitinib licensed to Lilly
2) Capmatinib licensed to Novartis

2017 Third-Quarter Financial Results

Revenues For the quarter ended September 30, 2017, net product revenues of Jakafi were $304 million as compared to $224 million for the same period in 2016, representing 36 percent growth. For the nine months ended September 30, 2017, net product revenues of Jakafi were $831 million as compared to $615 million for the same period in 2016, representing 35 percent growth. For the quarter ended September 30, 2017, net product revenues of Iclusig were $18 million as compared to $13 million for the same period in 2016, representing 42 percent growth. For the nine months ended September 30, 2017, net product revenues of Iclusig were $47 million as compared to $17 million for the same period in 2016[1].

For the quarter and nine months ended September 30, 2017, product royalties from sales of Jakavi, which has been out-licensed to Novartis outside of the United States, were $41 million and $104 million, respectively, as compared to $30 million and $77 million for the same periods in 2016. For the quarter and nine months ended September 30, 2017, product royalties from sales of Olumiant outside of the United States received from Lilly were $3 million, and $4 million, respectively.

For the quarter and nine months ended September 30, 2017, contract revenues were $15 million and $105 million, respectively, as compared to $3 million and $70 million for the same periods in 2016. The contract revenues in 2017 relate to milestone payments earned.

For the quarter ended September 30, 2017, total revenues were $382 million as compared to $269 million for the same period in 2016. For the nine months ended September 30, 2017, total revenues were $1.1 billion as compared to $779 million for the same period in 2016.

[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.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2017	**2016**	**Change**	**2017**	**2016**	**Change**
Revenues:						
Jakafi net product revenues	$ 303,929	$ 223,892	36%	$ 831,044	$615,285	35%
Iclusig net product revenues	18,100	12,731	42%	47,459	16,721	-
Product royalty revenues	44,487	29,626	50%	108,477	77,486	40%
Product-related revenues	366,516	266,249	38%	986,980	709,492	39%
Contract revenues	15,000	3,214	-	105,000	69,643	-
Other revenues	18	6	-	80	86	-
Total revenues	$ 381,534	$ 269,469	42%	$1,092,060	$779,221	40%

Research and development expenses Research and development expenses for the quarter and nine months ended September 30, 2017 were $270 million and $879 million, respectively, as compared to $143 million and $420 million for the same periods in 2016. The increase in research and development expenses was primarily due to the expansion of the Company's clinical portfolio as well as upfront and milestone expenses of $209 million related to our collaboration and license agreements with Agenus, Calithera and Merus. Included in research and development expenses for the quarter and nine months ended September 30, 2017 were non-cash expenses related to equity awards to our employees of $23 million and $68 million, respectively.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter and nine months ended September 30, 2017 were $91 million and $269 million, respectively, as compared to $76 million and $207 million for the same periods in 2016. Increased selling, general and administrative expenses were driven primarily by additional costs related to the commercialization of Jakafi and the geographic expansion in Europe. Included in selling, general and administrative expenses for the quarter and nine months ended September 30, 2017 were non-cash expenses related to equity awards to our employees of $12 million and $31 million, respectively.

Change in fair value of acquisition-related contingent consideration The change in fair value of acquisition-related contingent consideration for the quarter and nine months ended September 30, 2017 was a benefit of $16 million and $2 million, respectively, as compared to expense of $8 million and $10 million for the same periods in 2016. The change in fair value of acquisition-related contingent consideration 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 (loss) on long term investments Unrealized gain on long term investments for the quarter ended September 30, 2017 was $23 million as compared to $24 million for the same period in 2016. The unrealized loss on long term investments for the nine months ended September 30, 2017 was $2 million as compared to an unrealized gain of $20 million for the same period in 2016. The unrealized gain or loss on long term investments for the quarter and nine months ended September 30, 2017 represents the fair market value adjustments of the Company's investments in Agenus and Merus.

Expense related to senior note conversions Expense related to senior note conversions for the nine months ended September 30, 2017 was $55 million related to the conversions of certain of our 2018 and 2020 convertible senior notes.

Net income (loss) Net income for the quarter ended September 30, 2017 was $36 million, or $0.17 per basic and diluted share, as compared to net income of $37 million, or $0.20 per basic and $0.19 per diluted share for the same period in 2016. Net loss for the nine months ended September 30, 2017 was $164 million, or $0.81 per basic and diluted share, as compared to net income of $95 million, or $0.51 per basic and $0.49 per diluted share for the same period in 2016.

Cash, cash equivalents and marketable securities position As of September 30, 2017, cash, cash equivalents and marketable securities totaled $1.3 billion as compared to $809 million as of December 31, 2016. The increase in cash, cash equivalents and marketable securities from December 31, 2016 to September 30, 2017 is primarily due to the recent public offering of 4,945,000 shares of our common stock resulting in net proceeds of $649 million.

2017 Financial Guidance

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

	Current	Previous
Jakafi net product revenues	$1,125-$1,135 million	$1,090-$1,120 million
Iclusig net product revenues	$60-$65 million	Unchanged
Research and development expenses*	$1,250-$1,300 million	$1,050-$1,150 million
Selling, general and administrative expenses	$340-$360 million	Unchanged
Change in fair value of acquisition-related contingent consideration	$5-$7 million	$30-$35 million

* Includes upfront and milestone expenses of $359 million related to the amended Agenus collaboration, and the Merus, Calithera, and MacroGenics collaborations

Conference Call and Webcast Information

Incyte will hold its 2017 third-quarter financial results conference call and webcast this morning at 10:00 a.m. ET. To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13672268.

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, 13672268.

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, since acquired by Takeda Pharmaceutical Company Limited, 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 NDA for baricitinib for RA will be resubmitted to the FDA, how the FDA will classify the resubmission and the timing of the FDA's review, whether baricitinib will ever be approved in the U.S. for any indication and whether development of baricitinib in other indications will be successful or will continue as currently planned, including for atopic dermatitis; plans and expectations regarding our product pipeline and strategy (including without limitation plans and expectations relating to epacadostat, ruxolitinib, itacitinib, INCB50465 and INCB54828) - including timelines for advancing our 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, the number of potential clinical trials, and whether any specific program will be successful - and plans and expectations regarding development activities of our collaboration partners (including without limitation collaboration development activities relating to capmatinib and baricitinib); whether the Company's development portfolio will lead to transformational growth; and whether Incyte will become a world-class global biopharmaceutical company.

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; determinations made by the FDA; 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, 2017. 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product revenues, net	$322,029	$236,623	$ 878,503	$632,006
Product royalty revenues	44,487	29,626	108,477	77,486
Contract revenues	15,000	3,214	105,000	69,643
Other revenues	18	6	80	86
Total revenues	381,534	269,469	1,092,060	779,221
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	22,036	20,205	57,120	38,577
Research and development	269,612	143,184	879,423	420,276
Selling, general and administrative	91,271	75,776	268,577	207,166
Change in fair value of acquisition-related contingent consideration	(16,343)	8,012	(1,914)	10,283
Total costs and expenses	366,576	247,177	1,203,206	676,302
Income (loss) from operations	14,958	22,292	(111,146)	102,919
Interest and other income, net	5,555	1,188	10,884	3,818
Interest expense	(204)	(9,479)	(6,527)	(29,275)
Unrealized gain (loss) on long term investments	23,045	24,301	(2,343)	20,497
Expense related to senior note conversions	-	-	(54,881)	-
Income (loss) before provision (benefit) for income taxes	43,354	38,302	(164,013)	97,959
Provision (benefit) for income taxes	7,300	1,425	(500)	2,610
Net income (loss)	$ 36,054	$ 36,877	$(163,513)	$ 95,349
Net income (loss) per share:				
Basic	$ 0.17	$ 0.20	$ (0.81)	$ 0.51
Diluted	$ 0.17	$ 0.19	$ (0.81)	$ 0.49
Shares used in computing net income (loss) per share:				
Basic	206,796	188,029	202,399	187,632
Diluted	212,610	194,265	202,399	193,754

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

	September 30, 2017	December 31, 2016
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,281,389	$ 808,546
Restricted cash and investments	926	886
Accounts receivable	198,345	148,758
Property and equipment, net	246,825	167,679
Inventory	14,558	19,299
Prepaid expenses and other assets	65,360	35,412
Long term investments	169,020	31,987
Other intangible assets, net	242,285	258,437
In-process research and development	-	12,000
Goodwill	155,593	155,593
Total assets	$ 2,374,301	$ 1,638,597
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 308,840	$ 266,649
Convertible senior notes	23,711	651,481
Acquisition-related contingent consideration	284,000	301,000
Stockholders' equity	1,757,750	419,467
Total liabilities and stockholders' equity	$ 2,374,301	$ 1,638,597

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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