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

May 4, 2017

- *$251 million of 2017 first-quarter net product revenues from Jakafi® (ruxolitinib), representing 37 percent growth over the same period last year*
- *Expanded ECHO program for epacadostat to include multiple pivotal trials in patients with melanoma, non-small cell lung, head & neck, bladder, and renal cancers in combination with PD-1 inhibitors*
- *Olumiant® (baricitinib) approved by the European Commission for the treatment of moderate to severe active rheumatoid arthritis; Complete Response Letter (CRL) for baricitinib issued by the FDA*

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

WILMINGTON, Del.--(BUSINESS WIRE)--May 4, 2017-- Incyte Corporation (Nasdaq: INCY) today reports 2017 first-quarter 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; and now including royalties from European sales of Olumiant® (baricitinib) by Lilly.

Incyte continues to expand its development portfolio. The pivotal program studying ruxolitinib in patients with graft-versus-host disease (GVHD) is underway, and the pivotal program studying ruxolitinib in patients with essential thrombocythemia (ET) is expected to start soon. The Company recently announced details of its expanded collaboration with Merck, growing the pivotal program studying epacadostat in combination with pembrolizumab to a total of five tumor types. Additionally, Incyte expanded its collaboration with Bristol-Myers Squibb evaluating epacadostat in combination with nivolumab in pivotal studies in two tumor types. Data recently presented at the American Association for Cancer Research (AACR) meeting showcased the clinical profile of Incyte's selective FGFR1/2/3 inhibitor which is now in Phase 2 trials in three indications and which, if successful, may be registration-enabling.

"The strong growth of Jakafi is very exciting as we continue to see more patients benefiting from treatment in both approved indications," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "We believe that our clinical portfolio is progressing well, with epacadostat moving rapidly into multiple pivotal programs and numerous other programs in or planned to enter potentially registration-enabling studies."

Portfolio Update

Cancer – Targeted Therapies

In March, the first patient entered REACH2, the Novartis-sponsored randomized Phase 3 trial of ruxolitinib for the treatment of patients with steroid-refractory acute GVHD. REACH3, a Phase 3 trial of ruxolitinib as a treatment for patients with steroid-refractory chronic GVHD, is expected to begin in 2017. REACH3 is to be conducted in collaboration with Novartis.

In February, the first patient was dosed in the Phase 2 CITADEL-202 trial, studying the selective PI3Kδ inhibitor INCB50465 as monotherapy in patients with diffuse large B-cell lymphoma (DLBCL).

In April, initial clinical data from INCB54828, Incyte's selective FGFR1/2/3 inhibitor, was presented at the 2017 AACR meeting, including safety and efficacy in patients with bladder cancer, cholangiocarcinoma and 8p11 MPNs.

	Indication	Status Update
Ruxolitinib (JAK1/JAK2)	Steroid-refractory acute GVHD	Pivotal Phase 2 (REACH1) and Phase 3 (REACH2) underway
Ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD	Phase 3 (REACH3) 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)
INCB54828 (FGFR1/2/3)	Bladder cancer, cholangiocarcinoma; 8p11 MPNs	Phase 2 (FIGHT-201, FIGHT-202, FIGHT-203)
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 March 2017, Incyte and Merck announced the details of the expanded clinical development program investigating epacadostat with pembrolizumab. Incyte and Merck will move into pivotal programs in four additional tumor types beyond melanoma – non-small cell lung cancer (NSCLC), bladder, renal, and head & neck cancers – across six Phase 3 trials. These trials are expected to begin in 2017.

In April 2017, Incyte and Bristol-Myers Squibb announced an expanded collaborative clinical development program investigating epacadostat with nivolumab in pivotal programs for both NSCLC and head & neck cancer. Phase 3 trials are expected to begin in 2017.

	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)	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)
Epacadostat (IDO1)	NSCLC, bladder cancer	Phase 1/2 (ECHO-110) dose-escalation in combination with atezolizumab (PD-L1)
INCB01158 (ARG)[1]	Solid tumors	Phase 1/2 dose-escalation
INCSHR1210 (PD-1)[2]	Solid tumors	Phase 1/2 dose-escalation completed; enrollment suspended
INCAGN1876 (GITR)[3]	Solid tumors	Phase 1/2 dose-escalation
INCAGN1949 (OX40)[3]	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)

Notes:

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

Non-oncology

In January, Incyte initiated a Phase 2 trial of topical ruxolitinib for the treatment of patients with atopic dermatitis, and a Phase 2 trial in patients with vitiligo is expected to begin in 2017. After 24 weeks of treatment, Incyte has determined that data from the recently-completed randomized Phase 2 trial of topical ruxolitinib in patients with alopecia areata do not justify progression of the program into pivotal studies.

	Indication	Status Update
Topical ruxolitinib (JAK1/JAK2)	Atopic dermatitis	Phase 2
Topical ruxolitinib (JAK1/JAK2)	Vitiligo	Phase 2 expected to begin in 2017

Partnered

In February 2017, the European Commission approved Olumiant® (baricitinib) 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 anti-rheumatic drugs (DMARDs).

In April 2017, the FDA issued a complete response letter (CRL) for baricitinib in which the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. Incyte and Lilly disagree with the agency's conclusions and Incyte currently expects that Lilly will now engage with the FDA to discuss the agency's concerns and determine a potential path forward.

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

	Indication	Status Update
Baricitinib (JAK1/JAK2)[1]	Rheumatoid arthritis	Approved in Europe; CRL issued by FDA
Baricitinib (JAK1/JAK2)[1]	Psoriatic arthritis	Lilly expects Phase 3 to begin in 2017

Baricitinib (JAK1/JAK2)[1]	Atopic dermatitis, 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 First-Quarter Financial Results

Revenues For the quarter ended March 31, 2017, net product revenues of Jakafi were $251 million as compared to $183 million for the same period in 2016, representing 37 percent growth. For the quarter ended March 31, 2017, net product revenues of Iclusig were $14 million[1].

For the quarter ended March 31, 2017, product royalties from sales of Jakavi outside of the United States received from Novartis were $29 million as compared to $22 million for the same period in 2016. For the quarter ended March 31, 2017, product royalties from sales of Olumiant outside of the United States received from Lilly were $0.4 million.

For the quarter ended March 31, 2017, contract revenues were $90 million as compared to $58 million for the same period in 2016. The increase in contract revenues relates to milestone payments earned.

For the quarter ended March 31, 2017, total revenues were $384 million as compared to $263 million for the same period in 2016.

Year Over Year Revenue Growth
(in thousands, unaudited)

	Three Months Ended March 31,		%
	2017	**2016**	**Change**
Revenues:			
Jakafi net product revenue	$ 251,077	$ 183,267	37%
Iclusig net product revenue	13,730	-	-
Product royalty revenues	29,221	21,903	33%
Contract revenues	90,000	58,214	-
Other revenues	54	80	-
Total revenues	$ 384,082	$ 263,464	46%

Research and development expenses Research and development expenses for the quarter ended March 31, 2017 were $408 million as compared to $157 million for the same period in 2016. Included in research and development expenses for the quarter ended March 31, 2017 were non-cash expenses related to equity awards to our employees of $22 million. 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.

Selling, general and administrative expenses Selling, general and administrative expenses for the quarter ended March 31, 2017 were $87 million as compared to $65 million for the same period in 2016. Included in selling, general and administrative expenses for the quarter ended March 31, 2017 were non-cash expenses related to equity awards to our employees of $9 million. 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 for the quarter ended March 31, 2017 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 investments Unrealized loss on long term investments for the quarter ended March 31, 2017 were $6 million as compared to $3 million for the same period in 2016. The unrealized loss on long term investments for the quarter ended March 31, 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 quarter ended March 31, 2017 was $54 million related to the conversions of our 2018 and 2020 convertible senior notes.

Net income (loss) Net loss for the quarter ended March 31, 2017 was $187 million, or $0.96 per basic and diluted share, as compared to net income of $24 million, or $0.13 per basic and $0.12 per diluted share for the same period in 2016.

Cash, cash equivalents and marketable securities position As of March 31, 2017, cash, cash equivalents and marketable securities totaled $512 million as compared to $809 million as of December 31, 2016.

2017 Financial Guidance

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

	Current	Previous
Jakafi net product revenues	$1,020-$1,070 million	Unchanged
Iclusig net product revenues	$60-$65 million	Unchanged
Research and development expenses*	$1,000-$1,100 million	$990-$1,040 million
Selling, general and administrative expenses	$340-$360 million	Unchanged
Change in fair value of acquisition-related contingent consideration	$30-$35 million	Unchanged

* Includes upfront and milestone expenses of $209 million related to the amended Agenus collaboration, and the Merus and Calithera collaborations

Conference Call and Webcast Information

Incyte will hold its 2017 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, 13659569.

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, 13659569.

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 baricitinib for RA will be approved in the U.S., whether and when Lilly will pursue possible next steps towards seeking or achieving approval in the U.S. for baricitinib for RA, 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; whether we will receive any further milestones from Lilly in connection with baricitinib development; and plans and expectations regarding the Company’s product pipeline and strategy - including timelines for advancing its drug candidates (including without limitation epacadostat, ruxolitinib and itacitinib) 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-K for the year ended December 31, 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 March 31,	
	2017	**2016**
Revenues:		
Product revenues, net	$ 264,807	$183,267
Product royalty revenues	29,221	21,903
Contract revenues	90,000	58,214
Other revenues	54	80
Total revenues	384,082	263,464
Costs and expenses:		
Cost of product revenues (including definite-lived intangible amortization)	14,824	6,005
Research and development	407,972	156,824
Selling, general and administrative	87,234	64,596
Change in fair value of acquisition-related contingent consideration	7,356	-
Total costs and expenses	517,386	227,425
Income (loss) from operations	(133,304)	36,039
Interest and other income, net	1,204	1,492
Interest expense	(5,939)	(10,134)
Unrealized loss on long term investments	(5,814)	(2,950)
Expense related to senior note conversions	(54,130)	-
Income (loss) before provision (benefit) for income taxes	(197,983)	24,447
Provision (benefit) for income taxes	(10,900)	400
Net income (loss)	$(187,083)	$ 24,047
Net income (loss) per share:		
Basic	$ (0.96)	$ 0.13
Diluted	$ (0.96)	$ 0.12
Shares used in computing net income (loss) per share:		
Basic	195,260	187,184
Diluted	195,260	192,625

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

	March 31, 2017	**December 31, 2016**
ASSETS		
Cash, cash equivalents and marketable securities	$ 511,955	$ 808,546
Restricted cash and investments	902	886
Accounts receivable	244,975	148,758
Property and equipment, net	193,211	167,679
Inventory	18,509	19,299
Prepaid expenses and other assets	58,827	35,412
Long term investments	158,322	31,987
Other intangible assets, net	253,053	258,437
In-process research and development	12,000	12,000
Goodwill	155,593	155,593
Total assets	$1,607,347	$ 1,638,597

LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 295,809	$ 266,649
Convertible senior notes	41,604	651,481
Acquisition-related contingent consideration	304,000	301,000
Stockholders' equity	965,934	419,467
Total liabilities and stockholders' equity	$1,607,347	$ 1,638,597

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