



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

August 1, 2017

- \$276 million of 2017 second-quarter net product revenues from Jakafi® (ruxolitinib), representing 33 percent growth over the same period last year
- Proof-of-concept data for the combination of epacadostat plus PD-1 inhibition presented at the American Society of Clinical Oncology Annual Meeting (ASCO) 2017 across multiple tumor types; expanded Phase 3 program on track for planned initiation in 2017
- Multiple product candidates in late-stage clinical development illustrates transformational growth potential of Incyte's portfolio

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 1, 2017-- Incyte Corporation (Nasdaq: INCY) today reports 2017 second-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 Olumiant® (baricitinib) by Lilly. Recent highlights also include the initiation of two pivotal studies (ruxolitinib for treatment-refractory chronic graft versus host disease (GVHD); itacitinib for steroid-naïve acute GVHD), and the presentation of multiple data sets at ASCO 2017 supporting the expansion of the pivotal trial program for epacadostat.

"Revenue growth from Jakafi and Iclusig continues to be very robust, driven by strong demand, and we have also made significant progress across our clinical portfolio. As we look forward to the second half of 2017, we anticipate the publication of important data from our development candidates, as well as the initiation of multiple additional pivotal combination studies with epacadostat," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "Investment in innovation has created significant value for Incyte, our stakeholders and for the patients that our products treat. With strong revenue growth, a broad clinical development portfolio, comprehensive drug discovery capabilities and an expanded geographic footprint which now includes the U.S., Europe and Japan, we believe that we are well positioned for long-term value creation."

Portfolio Update

Cancer – Targeted Therapies

In July, the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for myeloproliferative neoplasms (MPNs) were published, and now include Jakafi as a recommended treatment for patients with myelofibrosis and patients with polycythemia vera who have had an inadequate response to first-line therapies, such as hydroxyurea.

In June, REACH3, a Phase 3 trial of ruxolitinib as a treatment for patients with steroid-refractory chronic GVHD, was initiated. REACH3 is being conducted in collaboration with Novartis.

RESET-272, the double-blind, randomized pivotal trial of ruxolitinib versus anagrelide for the treatment of patients with essential thrombocythemia who are resistant to or intolerant of hydroxyurea, is now open for enrollment.

GRAVITAS-301, the Phase 3 trial of itacitinib, Incyte's selective JAK1 inhibitor, in patients with treatment-naïve acute GVHD, began dosing in July.

Following a review of the clinical profiles of Incyte's two BRD inhibitors, INCB54329 and INCB57643, including data expected to be presented at medical meetings in the second half of 2017, the Company intends to focus future development efforts on INCB57643.

In June, Incyte initiated the Phase 1/2 dose-escalation trial of its FGFR4 inhibitor, INCB62079, in patients with hepatocellular carcinoma.

	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	Phase 2 (CITADEL-202)
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

Cancer – Immune Therapies

At ASCO 2017 in June, new data from the ECHO-202 and ECHO-204 Phase 1/2 trials of epacadostat plus PD-1 inhibitors were presented in multiple tumor types. These data formed the basis of the decisions to proceed into multiple Phase 3 trials, in collaboration with each of Merck and Bristol-Myers Squibb, respectively, as announced earlier this year.

In June 2017, Incyte and Roche/Genentech decided to close the ECHO-110 trial of epacadostat plus atezolizumab to further enrollment because of slow study recruitment.

	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)
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 June, Incyte initiated a Phase 2 trial of topical ruxolitinib for the treatment of patients with vitiligo.

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

Partnered

In July 2017, Lilly and Incyte announced that Japan's Ministry of Health, Labor and Welfare granted marketing approval for Olumiant for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies.

In July 2017, Lilly and Incyte announced that a resubmission to the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) for baricitinib will be delayed for a period anticipated to be a minimum of 18 months. The companies will be further discussing the path forward with the agency and evaluating options for resubmission, including the potential for an additional clinical study, as requested by the FDA.

Novartis has stated that it 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 and Japan; CRL issued by FDA
Baricitinib (JAK1/JAK2)¹	Psoriatic arthritis	Lilly no longer 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

Corporate Update

In June 2017, Lothar Finke, M.D. joined the Incyte Executive Management team as Head of Development Japan and General Manager, Japan. Dr. Finke was most recently the Head of Oncology Development and Medical Affairs Japan for Novartis where he was responsible for leading an integrated organization to support oncology development. He has significant experience developing drugs in all classes of oncology including immunology, targeted therapies and cell therapies in the EU, U.S., Canada, and Japan.

2017 Second-Quarter Financial Results

Revenues For the quarter ended June 30, 2017, net product revenues of Jakafi were \$276 million as compared to \$208 million for the same period in 2016, representing 33 percent growth. For the six months ended June 30, 2017, net product revenues of Jakafi were \$527 million as compared to \$391 million for the same period in 2016, representing 35 percent growth. For the quarter ended June 30, 2017, net product revenues of Iclusig were \$16 million as compared to \$4 million for the same period in 2016. For the six months ended June 30, 2017, net product revenues of Iclusig were \$29 million as compared to \$4 million for the same period in 2016¹.

For the quarter and six months ended June 30, 2017, product royalties from sales of Jakavi, which has been out-licensed to Novartis outside of the United States, were \$34 million and \$63 million, respectively, as compared to \$26 million and \$48 million for the same periods in 2016. For the quarter and six months ended June 30, 2017, product royalties from sales of Olumiant outside of the United States received from Lilly were \$1 million.

For the quarter and six months ended June 30, 2017, contract revenues were \$0 million and \$90 million, respectively, as compared to \$8 million and \$66 million for the same periods in 2016. These contract revenues relate to milestone payments earned.

For the quarter ended June 30, 2017, total revenues were \$326 million as compared to \$246 million for the same period in 2016. For the six months ended June 30, 2017, total revenues were \$711 million as compared to \$510 million for the same period in 2016.

Year Over Year Revenue Growth (in thousands, unaudited)

	Three Months Ended			Six Months Ended		
	June 30,		%	June 30,		%
	2017	2016		2017	2016	
Revenues:						
Jakafi net product revenue	\$ 276,038	\$ 208,126	33%	\$527,115	\$391,393	35%
Iclusig net product revenue	15,629	3,990	-	29,359	3,990	-
Product royalty revenues	34,769	25,958	34%	63,990	47,860	34%
Contract revenues	-	8,214	-	90,000	66,429	-
Other revenues	8	-	-	62	80	-
Total revenues	<u>\$ 326,444</u>	<u>\$ 246,288</u>	33%	<u>\$710,526</u>	<u>\$509,752</u>	39%

Research and development expenses Research and development expenses for the quarter and six months ended June 30, 2017 were \$202 million and \$610 million, respectively, as compared to \$120 million and \$277 million for the same periods in 2016. Included in research and development expenses for the quarter and six months ended June 30, 2017 were non-cash expenses related to equity awards to our employees of \$23 million and \$44 million, respectively. 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 and six months ended June 30, 2017 were \$90 million and \$177 million, respectively, as compared to \$67 million and \$131 million for the same periods in 2016. Included in selling, general and administrative expenses for the quarter and six months ended June 30, 2017 were non-cash expenses related to equity awards to our employees of \$11 million and \$20 million, respectively. Increased selling, general and administrative expenses were 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 for the quarter and six months ended June 30, 2017 were \$7 million and \$14 million, respectively, as compared to \$2 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 loss on long term investments Unrealized loss on long term investments for the quarter and six months ended June 30, 2017 were \$20

million and \$25 million, respectively, as compared to \$1 million and \$4 million for the same periods in 2016. The unrealized loss on long term investments for the quarter and six months ended June 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 quarter and six months ended June 30, 2017 were \$1 million and \$55 million, respectively, related to the conversions of certain of our 2018 and 2020 convertible senior notes.

Net income (loss) Net loss for the quarter ended June 30, 2017 was \$12 million, or \$0.06 per basic and diluted share, as compared to net income of \$34 million, or \$0.18 per basic and diluted share for the same period in 2016. Net loss for the six months ended June 30, 2017 was \$200 million, or \$1.00 per basic and diluted share, as compared to net income of \$58 million, or \$0.31 per basic and \$0.30 per diluted share for the same period in 2016.

Cash, cash equivalents and marketable securities position As of June 30, 2017, cash, cash equivalents and marketable securities totaled \$609 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	\$1,090-\$1,120 million	\$1,020-\$1,070 million
Iclusig net product revenues	\$60-\$65 million	Unchanged
Research and development expenses *	\$1,050-\$1,150 million	\$1,000-\$1,100 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 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, 13665688.

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, 13665688.

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 a new clinical trial will be undertaken for baricitinib for RA in the U.S., whether and when the NDA for baricitinib for RA will be resubmitted to the FDA, 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; 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 highly profitable 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 March 31, 2017. 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		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenues:				
Product revenues, net	\$ 291,667	\$ 212,116	\$ 556,474	\$ 395,383
Product royalty revenues	34,769	25,958	63,990	47,860
Contract revenues	-	8,214	90,000	66,429
Other revenues	8	-	62	80
Total revenues	<u>326,444</u>	<u>246,288</u>	<u>710,526</u>	<u>509,752</u>
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	20,260	12,367	35,084	18,372
Research and development	201,839	120,269	609,811	277,092
Selling, general and administrative	90,072	66,792	177,306	131,390
Change in fair value of acquisition-related contingent consideration	7,073	2,271	14,429	2,271
Total costs and expenses	<u>319,244</u>	<u>201,699</u>	<u>836,630</u>	<u>429,125</u>
Income (loss) from operations	7,200	44,589	(126,104)	80,627
Interest and other income, net	4,125	1,137	5,329	2,630
Interest expense	(384)	(9,662)	(6,323)	(19,796)
Unrealized loss on long term investments	(19,574)	(854)	(25,388)	(3,804)
Expense related to senior note conversions	(751)	-	(54,881)	-
Income (loss) before provision (benefit) for income taxes	(9,384)	35,210	(207,367)	59,657
Provision (benefit) for income taxes	3,100	785	(7,800)	1,185
Net income (loss)	<u>\$(12,484)</u>	<u>\$ 34,425</u>	<u>\$(199,567)</u>	<u>\$ 58,472</u>
Net income (loss) per share:				
Basic	\$ (0.06)	\$ 0.18	\$ (1.00)	\$ 0.31
Diluted	\$ (0.06)	\$ 0.18	\$ (1.00)	\$ 0.30
Shares used in computing net income (loss) per share:				
Basic	205,141	187,682	200,200	187,433
Diluted	205,141	193,015	200,200	192,820

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

	June 30,	December 31,
	2017	2016
ASSETS		
Cash, cash equivalents and marketable securities	\$ 608,606	\$ 808,546
Restricted cash and investments	943	886
Accounts receivable	169,516	148,758
Property and equipment, net	218,878	167,679
Inventory	14,837	19,299
Prepaid expenses and other assets	66,976	35,412
Long term investments	144,425	31,987
Other intangible assets, net	247,669	258,437
In-process research and development	12,000	12,000
Goodwill	155,593	155,593
Total assets	<u>\$1,639,443</u>	<u>\$ 1,638,597</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	\$ 283,180	\$ 266,649
Convertible senior notes	23,428	651,481
Acquisition-related contingent consideration	306,000	301,000
Stockholders' equity	1,026,835	419,467
Total liabilities and stockholders' equity	<u>\$1,639,443</u>	<u>\$ 1,638,597</u>

View source version on businesswire.com: <http://www.businesswire.com/news/home/20170801005504/en/>

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