Incyte Reports 2014 Second-Quarter Financial Results and Updates Shareholders on Key Clinical Programs

July 31, 2014

- *$84.0 million of 2014 second-quarter net product revenues from Jakafi® (ruxolitinib), representing 55 percent growth over the same period last year*
- *2014 guidance for Jakafi net product revenues increased to range of $330 million to $340 million, driven by strong underlying demand*
- *Timely initiation of key pipeline programs, including initiation of two pivotal trials of ruxolitinib in pancreatic cancer and three proof of concept trials of ruxolitinib in other solid tumors*
- *Multiple combination therapy clinical trial agreements signed for IDO1 inhibitor INCB24360, with first such trial initiated in July*

Conference Call Scheduled Today at 8:30 a.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 31, 2014-- Incyte Corporation (Nasdaq: INCY) today reported 2014 second-quarter financial results, including revenue from Jakafi® (ruxolitinib), which is approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis (MF). The Company highlighted its strong financial position, driven by growing Jakafi sales in the U.S. and Jakavi® (ruxolitinib) royalties outside the U.S., as well as the submission of the ruxolitinib supplemental New Drug Application (sNDA) in the U.S. for patients with uncontrolled polycythemia vera (PV). The Company also discussed its expanding clinical pipeline, which includes pivotal as well as proof of concept studies, and the multiple data presentations for the Company's product candidates that were made at the recent American Society of Clinical Oncology (ASCO) meeting. The Company also highlighted additional clinical trial agreements for its investigational IDO1 inhibitor INCB24360 with Bristol-Myers Squibb, AstraZeneca/MedImmune and Genentech, as well as the initiation of the clinical trial of INCB24360 in combination with Merck's pembrolizumab.

"We continue the successful commercialization of Jakafi in myelofibrosis, and I am encouraged by the rapid regulatory and clinical advances we are making across the breadth of our development pipeline," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "The field of oncology is evolving at an unprecedented pace, and Incyte's scientific and commercial progress serves to highlight our central position in the ongoing transformation in how cancer patients are treated."

2014 Second-Quarter Financial Results

Revenues

For the quarter ended June 30, 2014, net product revenues of Jakafi were $84.0 million as compared to $54.1 million for the same period in 2013, representing 55 percent growth. For the six months ended June 30, 2014, net product revenues were $153.7 million as compared to $102.4 million for the same period in 2013, representing 50 percent growth.

The Company now expects that 2014 net product revenues from Jakafi will be in the range of $330 million to $340 million, an increase from the previous range of $315 million to $335 million. This range excludes any product royalty revenues received from the Company's collaboration partner Novartis on sales of Jakavi® (ruxolitinib) outside the United States.

For the quarter and six months ended June 30, 2014, product royalties from sales of Jakavi® outside the United States received from Novartis were $12.3 million and $22.2 million, respectively, as compared to $5.8 million and $11.7 million, respectively, for the same periods in 2013.

For the quarter ended June 30, 2014, contract revenues were $3.2 million as compared to $41.7 million for the same period in 2013, which included a $25.0 million milestone related to our c-MET program and $13.5 million of deferred revenue amortization related to the Novartis upfront payment. For the six months ended June 30, 2014, contract revenues were $13.4 million as compared to $58.5 million for the same period in 2013. The decrease in contract revenues for the six months ended June 30, 2014 compared to the same period in 2013 relates to the Novartis upfront payment received under the collaboration being fully amortized at December 31, 2013, and by the $25.0 million milestone related to our c-MET program recognized in the second quarter of 2013, partially offset by the $7.0 million milestone related to our c-MET program recognized in the first quarter of 2014.

For the quarter ended June 30, 2014, total revenues were $99.6 million as compared to $101.7 million for the same period in 2013. For the six months ended June 30, 2014, total revenues were $189.4 million as compared to $172.8 million for the same period in 2013.

Non-Cash Stock Expense

Included in operating expenses for the quarter ended June 30, 2014, was $15.5 million of non-cash expense related to equity awards to our employees, of which $8.5 million was included in research and development expenses and $7.0 million was included in selling, general and administrative expenses. For the year to date, non-cash expense related to equity awards to our employees was $30.8 million, of which $16.8 million was included in research and development expenses and $14.0 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter and six months ended June 30, 2014, were $84.7 million and $160.3 million, respectively, as compared to $61.0 million and $113.7 million, respectively, for the same periods in 2013.

The increase in research and development expenses for the quarter and six months ended June 30, 2014, compared to the same prior year periods, was primarily due to the expansion of the Company's pipeline, which included the costs related to two Phase III trials of ruxolitinib in pancreatic cancer; Phase II trials of ruxolitinib in non-small cell lung cancer, colorectal cancer and breast cancer; a Phase II trial of INCB39110 in non-small cell lung cancer; and the Phase III program for baricitinib in rheumatoid arthritis.

Selling, general and administrative expenses for the quarter and six months ended June 30, 2014, were $40.9 million and $77.9 million, respectively, as compared to $23.2 million and $45.5 million, respectively, for the same periods in 2013.

Increased selling, general and administrative expenses for the quarter and six months ended June 30, 2014, compared to the same prior year periods reflected the additional costs related to the commercialization of Jakafi in MF, including the expansion in our field force, as well as preparation for the anticipated launch in PV.

Interest Expense

Interest expense for the quarter and six months ended June 30, 2014, was $11.4 million and $22.8 million, respectively, as compared to $10.3 million and $22.0 million, respectively, for the same periods in 2013. Included in interest expense for the quarter and six months ended June 30, 2014, were $8.9 million and $17.7 million, respectively, of non-cash charges to amortize the discount on the Company's 4.75% Convertible Senior Notes due 2015 (2015 Notes), 0.375% Convertible Senior Notes due 2018 and 1.25% Convertible Senior Notes due 2020, as compared to $6.2 million and $13.2 million, respectively, to amortize the discount on the Company's 2015 Notes for the same periods in 2013.

Net Loss

Net loss for the quarter ended June 30, 2014, was $36.9 million, or $0.22 per basic and diluted share, as compared to a net loss of $2.6 million, or $0.02 per basic and diluted share, for the same period in 2013. Net loss for the six months ended June 30, 2014, was $70.8 million, or $0.43 per basic and diluted share, as compared to a net loss of $18.2 million, or $0.13 per basic and diluted share, for the same period in 2013.

Cash and Marketable Securities Position

As of June 30, 2014, cash, cash equivalents and marketable securities totaled $508.8 million compared to $509.0 million as of December 31, 2013.

Recent Clinical Highlights

Jakafi® (ruxolitinib) – a JAK1 and JAK2 Inhibitor

Myeloproliferative Neoplasms

The product label for Jakafi was recently expanded to include overall survival data and additional safety and dosing information. This new information is based on three-year data from the two pivotal Phase III trials in myelofibrosis patients, COMFORT-I and II.

Positive data from RESPONSE, a Phase III trial conducted under a Special Protocol Assessment (SPA) from the FDA in collaboration with Novartis to evaluate ruxolitinib in patients with polycythemia vera (PV) who are resistant to, or intolerant of, hydroxyurea, were presented in an oral session at the ASCO annual meeting in June. The trial met its primary endpoint of achieving phlebotomy independence and reducing spleen size by 35 percent or more. The safety profile of ruxolitinib was generally consistent with previous studies. Global submissions seeking regulatory approval of ruxolitinib in uncontrolled PV are underway, and the sNDA was submitted to the FDA in June 2014.

As previously announced, the RELIEF trial measuring disease-related symptoms in patients with PV did not meet its primary endpoint of the proportion of subjects achieving a ≥ 50% reduction in a cluster of PV-related symptoms at week 16 compared to baseline, although positive trends in favor of ruxolitinib versus continued hydroxyurea were observed. Further analyses of RELIEF are underway to evaluate what factors may have contributed to a symptom control rate for patients on stable doses of hydroxyurea that was significantly higher than that seen in the best available therapy control arm of the RESPONSE trial, and which led to an underpowering of the RELIEF trial. Data from RELIEF are expected to be presented at an upcoming scientific meeting.

In July 2014 Jakavi® (ruxolitinib) received approval in Japan for the treatment of patients with myelofibrosis, triggering a $25 million milestone payment from Novartis. This milestone will be recognized as contract revenue in the third quarter of 2014. Novartis also continues to make progress in obtaining formal pricing and reimbursement approval for a third major European country. Once achieved, the Company will earn an additional $60 million milestone payment, which is expected to occur in the second half of 2014.

Solid Tumors

Full results from RECAP, a Phase II trial of ruxolitinib in combination with capecitabine in patients with metastatic pancreatic cancer, were presented in an oral session at ASCO in June. These data highlighted the beneficial effect of ruxolitinib in a pre-specified subgroup of pancreatic cancer patients with high levels of C-reactive protein (CRP), a well-established marker of systemic inflammation.

JANUS 1, a double-blind, placebo-controlled Phase III trial for advanced or metastatic pancreatic cancer, which is being conducted under an SPA, was initiated in March 2014. A second, nearly identical, Phase III trial (JANUS 2) was initiated in the second quarter of 2014. Both trials are designed to examine the safety and efficacy of ruxolitinib in pancreatic cancer patients with high levels of systemic inflammation.

The FDA has granted Fast Track designation for ruxolitinib for the treatment of patients with second-line pancreatic cancer. Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

Three additional blinded Phase II proof-of-concept trials of ruxolitinib focusing on survival in non-small cell lung cancer, breast cancer and colorectal cancer patients with high levels of systemic inflammation are also recruiting patients.

INCB39110 – a JAK1 Inhibitor

The clinical program to evaluate INCB39110, a selective JAK1 inhibitor, in solid tumors is now underway and will begin with two randomized, double-blind Phase II trials in non-small cell lung cancer. The first trial, in combination with docetaxel, is now recruiting patients and the second trial is planned to open later this year. Both trials will only include patients with high levels of systemic inflammation, with overall survival as a primary endpoint in each.

INCB24360 – an IDO1 Inhibitor

The Company believes that the optimal development strategy for its IDO1 inhibitor INCB24360 is in combination with other immuno-oncology agents, and a Phase I/II trial to evaluate the combination of INCB24360 and Merck's investigational anti-PD-1 immunotherapy, pembrolizumab (MK-3475), has been initiated. This trial is recruiting patients with previously treated metastatic and recurrent non-small cell lung cancer and other advanced or metastatic cancers.

During the second-quarter of 2014, two additional clinical collaboration agreements were signed to evaluate INCB24360 in combination with investigational checkpoint inhibitors. A Phase I/II trial of INCB24360 in combination with AstraZeneca/MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor MEDI4736 in multiple solid tumors including metastatic melanoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck and pancreatic cancer is expected to begin in 2014. A Phase I/II trial in combination with Bristol-Myers Squibb's investigational PD-1 immune checkpoint inhibitor nivolumab in multiple tumor types, potentially including melanoma, non-small cell lung, ovarian, colorectal, squamous cell carcinoma of the head and neck and diffuse large B-cell lymphoma, is also expected to begin in 2014.

In July 2014, the Company entered into a clinical trial agreement with Genentech to evaluate the safety, tolerability and preliminary efficacy of INCB24360 in combination with Genentech's PD-L1 immune checkpoint inhibitor, MPDL3280A in patients with non-small cell lung cancer.

INCB24360 is currently being evaluated in a Phase I/II trial in combination with ipilimumab for metastatic melanoma. Preliminary data from this trial were presented as part of a poster discussion at ASCO in June, and the trial continues to recruit patients into the dose escalation phase of the study.

INCB40093 – a PI3K-delta Inhibitor

INCB40093 has completed a Phase I monotherapy dose-escalation trial in patients with B-lymphoid malignancies, and the study has proceeded into the dose-expansion phase. A second trial, which started in January 2014, is evaluating INCB40093 in combination with the Company's JAK1 inhibitor, INCB39110.

Baricitinib – a JAK1 and JAK2 Inhibitor

The Phase III clinical program to evaluate baricitinib in patients with rheumatoid arthritis, being conducted by the Company's collaboration partner Lilly, is ongoing, with the first of four Phase III studies due to complete later in 2014.

INC280 – a c-MET Inhibitor

Under the Incyte-Novartis collaboration and license agreement, Novartis has licensed INC280 for worldwide development and commercialization. Novartis is conducting a Phase II trial to evaluate INC280 as monotherapy in advanced c-MET positive hepatocellular carcinoma and a Phase II trial to evaluate INC280 in c-MET positive /EGFR-TKI-resistant non-small cell lung cancer.

Novartis is also conducting Phase II trials in c-MET dependent advanced solid malignancies.

Conference Call Information

Incyte will hold its 2014 second-quarter financial results conference call this morning at 8:30 a.m. ET. To access the conference call, please dial 877-407-8037 for domestic callers or 201-689-8037 for international callers. When prompted, provide the conference identification number, 13586309.

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, 13586309.

The conference call will also be webcast live and can be accessed at www.incyte.com under Investor Relations – Events and Webcasts.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs, primarily for oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

About Jakafi® (ruxolitinib)

Jakafi is a prescription medicine approved by the U.S. Food and Drug Administration to treat 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.

Important Safety Information

Jakafi can cause serious side effects including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had liver or kidney problems, are on dialysis, or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.incyte.com, which includes a more complete discussion of the risks associated with Jakafi.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements regarding financial guidance about expected net product revenues; the Company's view of its regulatory and clinical advances and its scientific and commercial progress; the Company's plans and expectations with respect to Jakafi ® (ruxolitinib), including its potential efficacy and therapeutic and commercial value; the Company's expectation to present the data from the RELIEF trial at an upcoming scientific meeting; Novartis continuing to make progress in obtaining formal pricing and reimbursement approval for Jakavi® (ruxolitinib) in a third major European country and expecting this to occur in the second half of 2014, and the Company earning an additional $60 million milestone payment once achieved; the Company's plans for INCB39110 to initiate the second Phase II trial in patients with non-small cell lung cancer later in the year; the Company's expectation that the first Phase III study conducted by its collaboration partner Lilly evaluating baricitinib in rheumatoid arthritis will complete later in 2014; and the Company's expectation to initiate Phase I/II trials evaluating the combination of INCB24360 and MEDI4736 and INCB24360 and nivolumab later in 2014, contain predictions, estimates and other forward-looking statements.

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 Jakafi, the acceptance of Jakafi in the marketplace, risks related to market competition, the results of further analyses of trial results, the results of further research and development, risks and uncertainties associated with sales, marketing and distribution requirements, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, 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, risks associated with the Company's dependence on its relationships with its collaboration partners, 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, 2014. Incyte 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,	
	2014	2013	2014	2013
Revenues:				
Product revenues, net	$ 84,025	$ 54,099	$153,676	$102,388
Product royalty revenues	12,340	5,800	22,166	11,709
Contract revenues	3,214	41,737	13,429	58,474
Other revenues	3	39	103	181
Total revenues	99,582	101,675	189,374	172,752
Costs and expenses:				
Cost of product revenues	187	157	355	308
Research and development	84,683	60,950	160,269	113,713
Selling, general and administrative	40,899	23,249	77,873	45,509
Total costs and expenses	125,769	84,356	238,497	159,530
Income (loss) from operations	(26,187)	17,319	(49,123)	13,222

Interest and other income, net	790	245	1,526	444
Interest expense	(11,406)	(10,293)	(22,849)	(22,022)
Debt exchange expense	-	(9,771)	(265)	(9,771)
Loss before income taxes	(36,803)	(2,500)	(70,711)	(18,127)
Provision for income taxes	70	71	119	113
Net loss	$ (36,873)	$ (2,571)	$(70,830)	$(18,240)
Net loss per basic and diluted share	$ (0.22)	$ (0.02)	$ (0.43)	$ (0.13)
Shares used in computing basic and diluted net loss per share	167,914	142,284	166,636	138,315

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	June 30, 2014 (unaudited)	December 31, 2013
Cash, cash equivalents, and short-term marketable securities	508,753	509,004
Accounts receivable, net	47,205	35,374
Total assets	679,107	629,568
Convertible senior notes(1)	673,315	661,567
Total stockholders' deficit	(170,998)	(193,108)

(1) Net of unamortized debt discount of $168.3 million and $185.0 million at June 30, 2014 and December 31, 2013, respectively.

Source: Incyte Corporation

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