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

May 1, 2014

- *$69.7 million of 2014 first-quarter net product revenues from Jakafi® (ruxolitinib); 6 percent increase in underlying demand over fourth-quarter 2013*
- Positive top-line results from Phase III study of ruxolitinib in patients with polycythemia vera keep sNDA filing on track for second quarter 2014
- Abstracts for ruxolitinib in pancreatic cancer and polycythemia vera and for IDO1 inhibitor INCB24360 in melanoma accepted for presentation at ASCO
- Pivotal Phase III trial of ruxolitinib in patients with advanced pancreatic cancer initiated in addition to multiple other clinical trials that significantly broaden pipeline

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

WILMINGTON, Del.--(BUSINESS WIRE)--May 1, 2014-- Incyte Corporation (Nasdaq: INCY) today reported 2014 first-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 also highlighted multiple achievements in its clinical programs, including positive top-line results from RESPONSE, a pivotal Phase III study of ruxolitinib in patients with uncontrolled polycythemia vera (PV); the initiation of its first of two Phase III trials of ruxolitinib in patients with advanced or metastatic pancreatic cancer; and the finalization of the protocol for the Phase I/II trial combining its investigational IDO1 inhibitor, INCB24360, with Merck's investigational anti-PD-1 immunotherapy, MK-3475.

"Underlying demand for Jakafi in myelofibrosis continues to grow, and the positive results from the pivotal Phase III trial, RESPONSE, support our confidence in the potential value that ruxolitinib can bring to patients with uncontrolled polycythemia vera," stated Hervé Hoppenot, Incyte's President and Chief Executive Officer. "Additionally, we're strengthening our existing programs in JAK inhibition with new indications and combinations, advancing our novel IDO1 inhibitor in the rapidly evolving field of immunotherapy, and progressing with clinical trials with our own PI3K-delta inhibitor."

**2014 First-Quarter Financial Results**

***Revenues***

For the quarter ended March 31, 2014, net product revenues of Jakafi were $69.7 million as compared to $48.3 million for the same period in 2013, representing 44 percent growth.

For the quarter ended March 31, 2014, product royalties from sales of Jakavi® (ruxolitinib) outside the United States received from the Company's collaboration partner Novartis were $9.8 million as compared to $5.9 million for the same period in 2013.

For the quarter ended March 31, 2014, contract revenues were $10.2 million as compared to $16.7 million for the same period in 2013. Included in contract revenues for the quarter ended March 31, 2014, was a $7.0 million milestone earned related to c-MET inhibitor INC280 under the Company's collaboration with Novartis. The decrease in 2014 contract revenues compared to the same period in 2013 relates to the Novartis upfront payment received under the collaboration being fully amortized at December 31, 2013, partially offset by the $7.0 million milestone earned related to INC280 under the collaboration with Novartis.

For the quarter ended March 31, 2014, total revenues were $89.8 million as compared to $71.1 million for the same period in 2013.

***Non-Cash Stock Expense***

Included in operating expenses for the quarter ended March 31, 2014, was $15.3 million of non-cash expense related to equity awards to our employees, of which $8.3 million was included in research and development expenses and $7.0 million was included in selling, general and administrative expenses.

***Operating Expenses***

Research and development expenses for the quarter ended March 31, 2014, were $75.6 million as compared to $52.8 million for the same period in 2013.

The increase in research and development expenses for the quarter ended March 31, 2014, compared to the comparable prior year period, 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 ended March 31, 2014, were $37.0 million as compared to $22.3 million for the same

period in 2013.

Increased selling, general and administrative expenses for the quarter ended March 31, 2014, compared to the comparable prior year period reflected the additional costs related to the commercialization of Jakafi in MF and preparation for the anticipated launch in PV.

***Interest Expense and Convertible Senior Notes***

Interest expense for the quarter ended March 31, 2014, was $11.4 million as compared to $11.7 million for the same period in 2013. Included in interest expense for the quarter ended March 31, 2014, was $8.8 million 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 $7.0 million to amortize the discount on the Company's 2015 Notes for the same period in 2013.

During the quarter, the Company entered into a negotiated agreement with a holder of the 2015 Notes pursuant to which the holder agreed to exchange $4.9 million aggregate principal amount of the 2015 Notes for the shares of the Company's stock into which the 2015 Notes were convertible, aggregating 0.6 million shares, and $0.3 million in cash. The Company recorded $0.3 million in debt exchange expense on senior note conversions for the quarter ended March 31, 2014.

***Net Loss***

Net loss for the quarter ended March 31, 2014, was $34.0 million, or $0.21 per basic and diluted share, as compared to a net loss of $15.7 million, or $0.12 per basic and diluted share, for the same period in 2013. The increase in net loss in the first quarter of 2014 as compared to the same period of 2013 is primarily due to the Company's broad investment in its clinical pipeline and additional costs related to the commercialization of Jakafi in MF and preparation for the anticipated launch in PV.

***Cash and Marketable Securities Position***

As of March 31, 2014, cash, cash equivalents and marketable securities totaled $519.2 million compared to $509.0 million as of December 31, 2013.

**Recent Clinical Highlights**

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

*Myeloproliferative Neoplasms*

RESPONSE, a Phase III trial conducted under a Special Protocol Assessment (SPA) in collaboration with Novartis to evaluate ruxolitinib in patients with PV who are resistant to or intolerant of hydroxyurea, met its primary endpoint of achieving phlebotomy independence and reducing spleen size by 35 percent or more. Additionally, the safety profile of ruxolitinib was generally consistent with previous studies. The filing of a supplemental new drug application with the FDA is expected in the second quarter of 2014.

RESPONSE data will be presented in an oral session at the American Society of Clinical Oncology (ASCO) annual meeting in June.

Data for RELIEF, a Phase III trial measuring disease-related symptoms in patients with PV, are expected in mid-2014, followed by presentation at an upcoming scientific meeting.

*Solid Tumors*

The results from RECAP, the Phase II trial of ruxolitinib in combination with capecitabine in metastatic pancreatic cancer, will be presented in an oral session at ASCO in June.

JANUS 1, a double-blinded, 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) is planned to begin in the second quarter of 2014. Both trials are designed to examine the subgroup identified in the Phase II clinical trial, RECAP.

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 among patients in the subgroup identified in RECAP are open, with first patients receiving ruxolitinib in the colorectal cancer trial.

INCB39110 – a JAK1 Inhibitor

The clinical program to evaluate INCB39110 in solid tumors is planned to start with two randomized, double-blind Phase II trials in non-small cell lung cancer. The first trial is expected to initiate in the second quarter of 2014; the second trial is planned for later this year. Both trials will only include patients in the subgroup identified in RECAP with overall survival as the primary endpoint.

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.

Phase II trials in patients with moderate-to-severe psoriasis and patients with diabetic nephropathy are also ongoing. Results for the psoriasis trial were presented in early 2014, and results for the diabetic nephropathy trial are anticipated in 2015.

INCB24360 – an IDO1 Inhibitor

INCB24360 is currently being evaluated in a Phase I/II trial in combination with ipilimumab for metastatic melanoma and in a Phase II trial as monotherapy for ovarian cancer.

Preliminary data from the combination trial will be presented as part of a poster discussion at ASCO in June.

The Investigational New Drug application for a Phase I/II trial to evaluate the combination of INCB24360 and Merck's investigational anti-PD-1 immunotherapy, MK-3475, in previously treated metastatic and recurrent non-small cell lung cancer and other advanced or metastatic cancers has been cleared by the FDA, and the trial is expected to initiate in the second quarter of 2014.

INCB40093 – a PI3K-delta Inhibitor

INCB40093 is currently in a Phase I dose-escalation trial in patients with B-lymphoid malignancies. A second trial, which started in January 2014, is evaluating INCB40093 in combination with the Company's JAK1 inhibitor, INCB39110.

INC280 – a c-MET Inhibitor

Under the Incyte-Novartis collaboration and license agreement, Novartis is conducting a Phase II trial to evaluate INC280 as monotherapy in advanced c-MET positive hepatocellular carcinoma. In addition, the initiation of a Phase II trial to evaluate INC280 in a second indication, c-MET positive/EGFR-TKI-resistant non-small cell lung cancer, triggered a $7.0 million milestone from Novartis.

Additionally, there are ongoing Phase II trials in c-MET dependent advanced solid malignancies.

**Conference Call Information**

Incyte will hold its 2014 first-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, 13580001.

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, 13580001.

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 experienced in the discovery, development and commercialization of proprietary small molecule drugs focused primarily on oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

**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. Do not drink grapefruit juice while taking 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.jakafi.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 the potential value that Jakafi® (ruxolitinib) can bring to patients with uncontrolled polycythemia vera; the Company's plans and expectations with respect to Jakafi, including its potential efficacy and therapeutic and commercial value; the Company's expectation to file a supplemental new drug application for ruxolitinib for polycythemia vera in the second quarter of 2014; the Company's expectation of data from the RELIEF trial in mid-2014 and their presentation at a scientific meeting; the Company's plans to begin the second Phase III trial of ruxolitinib in advanced or metastatic pancreatic cancer in the second quarter of 2014; the Company's plans for INCB39110 to initiate two Phase II trials in patients with non-small cell lung cancer, one in the second quarter of 2014 and one later in the year; the Company's expectation of results from the trials conducted by its collaboration partner Lilly evaluating baricitinib in patients with diabetic nephropathy in 2015; and the Company's expectation to initiate a Phase I/II trial evaluating the combination of INCB24360 and MK-3475 in the second quarter of 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 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-K for the year ended December 31, 2013.

**INCYTE CORPORATION**
**Condensed Consolidated Statements of Operations**
(unaudited, in thousands, except per share amounts)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2014** | **2013** |
| Revenues: | | |
| Product revenues, net | $ 69,651 | $ 48,289 |
| Product royalty revenues | 9,826 | 5,909 |
| Contract revenues | 10,214 | 16,737 |
| Other revenues | 101 | 142 |
| Total revenues | 89,792 | 71,077 |
| Costs and expenses: | | |
| Cost of product revenues | 168 | 150 |
| Research and development | 75,585 | 52,763 |
| Selling, general and administrative | 36,974 | 22,261 |
| Total costs and expenses | 112,727 | 75,174 |
| Loss from operations | (22,935) | (4,097) |
| Interest and other income, net | 735 | 199 |
| Interest expense | (11,443) | (11,728) |
| Debt exchange expense on senior note conversions | (265) | - |
| Loss before provision for income taxes | (33,908) | (15,626) |
| Provision for income taxes | 49 | 43 |
| Net loss | $(33,957) | $(15,669) |
| Basic and diluted net loss per share | $ (0.21) | $ (0.12) |
| Shares used in computing basic and diluted Net loss per share | 165,357 | 134,345 |

**INCYTE CORPORATION**
**Condensed Consolidated Balance Sheet Data**
(in thousands)

| | **March 31, 2014 (unaudited)** | **December 31, 2013** |
|---|---|---|
| Cash, cash equivalents, and short-term marketable securities | $ 519,231 | $ 509,004 |
| Accounts receivable, net | 46,394 | 35,374 |
| Total assets | 666,826 | 629,568 |
| Convertible senior notes(1) | 665,222 | 661,567 |
| Total stockholders' deficit | (162,422) | (193,108) |

(1) Net of unamortized debt discount of $176.4 million and $185.0 million at March 31, 2014, and December 31, 2013, respectively.

Source: Incyte Corporation

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