

Incyte Reports 2012 Third-Quarter Financial Results; Updates Shareholders on Launch of Jakafi and Lead Clinical Programs

November 1, 2012

- \$43.7 million of Jakafi® (ruxolitinib) recognized as third-quarter U.S. net product revenue including \$9.0 million of previously deferred revenue
- Third quarter dispenses to patients increased 16 percent over second quarter
- Ruxolitinib approved for use in the European Union

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

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 1, 2012-- Incyte Corporation (Nasdaq: INCY) today reported third-quarter 2012 financial results, including revenue from its first commercial product, Jakafi® (ruxolitinib), which was approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis (MF) in November 2011. Novartis, the Company's collaboration partner, announced that Jakafi, marketed as Jakavi® outside the United States, received approval from the European Commission for the treatment of disease-related splenomegaly or symptoms in adult patients with primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF. Jakafi/Jakavi is the first medicine to receive FDA and European Commission approval to treat patients with myelofibrosis and the first JAK inhibitor to be approved for any indication.

"We're encouraged by the underlying demand for Jakafi, and we are building a strong foundation for long-term growth. With continued efforts to expand the use of Jakafi among new and existing prescribers, extensive educational efforts around the optimal use of Jakafi, and additional data being presented at the upcoming American Society of Hematology annual meeting, we're confident that we will continue to see steady, consistent growth," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer.

2012 Third-Quarter Financial Results

Product Revenues

For the quarter and nine months ended September 30, 2012, net product revenues of Jakafi were \$43.7 million and \$92.7 million, respectively.

As expected, in the third quarter, the Company transitioned to the sell-in revenue recognition method from the sell-through method. Under the sell-in method, revenue is recognized when product is received by the specialty pharmacy, whereas under the sell-through method, revenue is recognized when the specialty pharmacy sends product to the patient, which reflects clinical demand. As a result, the \$43.7 million of net product revenues for the third quarter of 2012 included \$9.0 million of previously deferred revenue, representing product held by the specialty pharmacies at June 30, 2012.

For comparative purposes, the following table presents the Company's net product revenues as recognized for the three months ended March 31, 2012, and June 30, 2012, under the sell-through method, and as if the Company were still using the sell-through method for the three months ended September 30, 2012, which reflects a 16 percent increase in dispenses to patients from the second quarter to the third quarter:

<i>Sell-Through Method</i>	Three Months Ended March 31, 2012	Three Months Ended June 30, 2012	Three Months Ended September 30, 2012
Product revenues, net (in millions)	\$ 19.3	\$ 29.7	\$ 34.5*

* The \$34.5 million excludes \$9.0 million of previously deferred revenue and \$0.2 million of gross-to-net adjustments and changes in inventory levels at the specialty pharmacies during the quarter.

2012 Guidance Update

The Company is updating its 2012 guidance and now anticipates that Jakafi net product revenues will be in the range of \$130 million to \$135 million, a change from the previous range of \$120 million to \$135 million.

Total Revenues

Total revenues for the quarter and nine months ended September 30, 2012, were \$60.5 million and \$183.2 million, respectively, as compared to \$16.8 million and \$65.6 million, respectively, for the same periods in 2011. Included in total revenues for the quarter and nine months ended September 30, 2012, were net product revenues of \$43.7 million and \$92.7 million, respectively.

Included in total revenues for the nine months ended September 30, 2012, was a \$40 million European Union regulatory milestone payment received from Novartis related to Jakavi. Included in total revenues for the nine months ended September 30, 2011, was a \$15 million milestone payment received from Novartis related to INCB28060.

Net Loss

Net loss for the quarter ended September 30, 2012, was \$21.7 million, or \$0.17 per basic and diluted share, as compared to \$53.1 million, or \$0.42 per basic and diluted share, for the same period in 2011. Net loss for the nine months ended September 30, 2012, was \$63.1 million, or \$0.49 per basic and diluted share, as compared to a net loss of \$131.5 million, or \$1.05 per basic and diluted share, for the same period in 2011. Included in net loss for the nine months ended September 30, 2012, was a \$40 million European Union regulatory milestone payment received from Novartis related to Jakafi. Included in net loss for the nine months ended September 30, 2011, was a \$15 million milestone payment received from Novartis related to INCB28060.

Also included in net loss for the quarter and nine months ended September 30, 2012, were \$9.5 million and \$29.4 million, respectively, of non-cash expenses related to the impact of expensing employee stock options, compared to \$7.4 million and \$21.5 million, respectively, for the same periods in 2011.

Operating Expenses

Research and development expenses for the quarter and nine months ended September 30, 2012, were \$50.1 million and \$150.6 million, respectively, as compared to \$44.6 million and \$126.8 million, respectively, for the same periods in 2011. Included in research and development expenses for the quarter and nine months ended September 30, 2012, were non-cash expenses of \$6.4 million and \$19.6 million, respectively, related to the impact of expensing employee stock options, as compared to \$4.8 million and \$14.0 million, respectively, for the same periods in 2011.

The increases in research and development expenses for the quarter and nine months ended September 30, 2012, compared to the prior year periods were primarily a result of increased clinical development costs related to the advancement of the Company's pipeline and increased non-cash employee stock option expense. The Company expects its research and development expenses to vary from period to period, mainly due to the timing of its clinical development activities.

Selling, general and administrative expenses for the quarter and nine months ended September 30, 2012, were \$20.5 million and \$61.6 million, respectively, as compared to \$14.3 million and \$37.1 million, respectively, for the same periods in 2011. Included in selling, general and administrative expenses for the quarter and nine months ended September 30, 2012, were non-cash expenses of \$3.1 million and \$9.8 million, respectively, related to the impact of expensing employee stock options, as compared to \$2.6 million and \$7.5 million, respectively, for the same periods in 2011.

Increased selling, general and administrative expenses for the quarter and nine months ended September 30, 2012, compared to the prior year periods reflected the additional costs related to the Company's sales force and the commercialization efforts for the launch of Jakafi.

Interest Expense

Interest expense for the quarter and nine months ended September 30, 2012, was \$11.6 million and \$34.3 million, respectively, as compared to \$11.0 million and \$32.7 million, respectively, for the comparable periods in 2011. Included in interest expense for the quarter and nine months ended September 30, 2012, were \$6.8 million and \$20.0 million, respectively, of non-cash charges to amortize the discount on the Company's 4.75% Convertible Senior Notes due 2015, as compared to \$6.3 million and \$18.4 million, respectively, for the same periods in 2011.

Cash Position

As of September 30, 2012, cash, cash equivalents and marketable securities totaled \$243.6 million compared to \$277.6 million as of December 31, 2011. These amounts exclude \$9.5 million and \$19.0 million, as of September 30, 2012, and December 31, 2011, respectively, of restricted cash and investments held in an escrow account reserved for interest payments through October 2012 on the 4.75% Convertible Senior Notes.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

- The use of Jakafi to treat patients with intermediate or high-risk myelofibrosis (MF) is further supported by presentations to be made at the American Society of Hematology annual meeting in December, including updates from COMFORT-I and COMFORT-II.
 - Verstovsek, S, et al. *Long-Term Outcome of Ruxolitinib Treatment in Patients with Myelofibrosis: Durable Reductions in Spleen Volume, Improvements in Quality of Life, and Overall Survival Advantage in Comfort-I*. Dec. 10, 2012, at 6:30 p.m.
 - Cervantes, F, et al. *Long-Term Safety, Efficacy, and Survival Findings From Comfort-II, a Phase 3 Study Comparing Ruxolitinib with Best Available Therapy (BAT) for the Treatment of Myelofibrosis (MF)*. Dec. 10, 2012, at 6:45 p.m.
 - Vannucchi, A, et al. *Reductions in JAK2 V617F Allele Burden with Ruxolitinib Treatment in Comfort-II, A Phase 3 Study Comparing the Efficacy and Safety of Ruxolitinib with Best Available Therapy (BAT)*. Dec. 10, 2012, at 7 p.m.
- Two Phase III clinical trials (RESPONSE and RELIEF), in partnership with Novartis, are underway to evaluate ruxolitinib in patients with polycythemia vera (PV) with results expected to be part of a supplemental new drug application submission in 2014. The FDA has granted fast track designation for PV, specifically for the treatment of patients with PV who are resistant to or intolerant of hydroxyurea.
- A randomized Phase II trial of ruxolitinib in combination with capecitabine is actively recruiting patients with recurrent or treatment refractory metastatic pancreatic cancer (the RECAP trial). The RECAP trial is designed to enroll approximately 130 patients by late 2012, with final results expected in the second half of 2013.
- Multiple investigator-sponsored trials evaluating ruxolitinib are ongoing, including two Phase I/II trials in adults with

advanced hematologic malignancies (acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome and chronic myelogenous leukemia) and relapsed or refractory acute leukemia; a Phase I/II trial in children with hematologic malignancies and solid tumors; and a Phase II trial in patients with lymphoma. In addition, the first of several planned investigator-sponsored Phase II trials to evaluate ruxolitinib in treating patients with breast cancer was recently initiated.

Baricitinib, formerly known as LY3009104 (INCB28050) - a JAK1 and JAK2 Inhibitor

- Data from the six-month Phase IIb trial of baricitinib in patients with rheumatoid arthritis, conducted by our collaboration partner Eli Lilly and Company, will be presented at the American College of Rheumatology Annual Scientific Meeting in November 2012.
- A Phase III trial of baricitinib in patients with rheumatoid arthritis, conducted by Lilly, began screening patients in October 2012.
- A Phase IIb trial in patients with moderate to severe psoriasis, conducted by Lilly, is ongoing with primary endpoint results expected in 2013.
- A Phase II trial in patients with diabetic nephropathy, conducted by Lilly, was initiated in August 2012, and results are expected in 2014.

INCB28060 (also known as INC280) – a c-MET Inhibitor

- The initial Phase I trial in patients with solid tumors is nearing completion. This compound is licensed to Novartis as part of the Incyte-Novartis collaboration, and further development will be conducted by Novartis.

INCB24360 – an Indoleamine Dioxygenase-1 (IDO1) Inhibitor

- INCB24360 is currently in Phase I/II clinical development for metastatic melanoma in combination with ipilimumab and as monotherapy for ovarian cancer.

Early-Stage Development and Discovery Programs

- Several early development and discovery programs in oncology and inflammation are also ongoing.

Conference Call Information

Incyte will hold its third-quarter 2012 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, 401502.

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, 401502.

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 for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

About Jakafi

Jakafi is a prescription medicine used to treat people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF.

Important Safety Information

- Treatment with Jakafi can cause hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia, which are each dose-related effects, with the most frequent being thrombocytopenia and anemia. A complete blood count must be performed before initiating therapy with Jakafi. Complete blood counts should be monitored as clinically indicated and dosing adjusted as required. The three most frequent non-hematologic adverse reactions were bruising, dizziness and headache
- Patients with platelet counts $<200 \times 10^9/L$ at the start of therapy are more likely to develop thrombocytopenia during treatment. Thrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi. If clinically indicated, platelet transfusions may be administered
- Patients developing anemia may require blood transfusions. Dose modifications of Jakafi for patients developing anemia may also be considered

- Neutropenia (ANC $<0.5 \times 10^9/L$) was generally reversible and was managed by temporarily withholding Jakafi
- Patients should be assessed for the risk of developing serious bacterial, mycobacterial, fungal and viral infections. Active serious infections should have resolved before starting Jakafi. Physicians should carefully observe patients receiving Jakafi for signs and symptoms of infection (including herpes zoster) and initiate appropriate treatment promptly
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or in patients with renal or hepatic impairment [see *Dosage and Administration*]. Patients should be closely monitored and the dose titrated based on safety and efficacy
- There are no adequate and well-controlled studies of Jakafi in pregnant women. Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus
- Women taking Jakafi should not breast-feed. Discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother

For Full Prescribing Information for Jakafi, visit www.Jakafi.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements regarding our plans and expectations with respect to Jakafi (ruxolitinib), including the potential efficacy and therapeutic and commercial value of Jakafi, our expectation regarding continued steady, consistent growth, our expectation that results from the RESPONSE and RELIEF trials are expected to be part of a sNDA submission in 2014, our expectation that the RECAP trial will enroll approximately 130 patients by late 2012 with final results expected in the second half of 2013, our expectation that results from the trials conducted by our collaboration partner Eli Lilly and Company evaluating baricitinib in patients with moderate to severe psoriasis and diabetic nephropathy will be available in 2013 and 2014, respectively, our expectation that the initial Phase I trial evaluating INCB28060 is nearing completion, updated financial guidance about expected net product revenues, and expectations regarding variations in research and development expenses, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte'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 or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, risks associated with Incyte's dependence on its relationships with its collaboration partners, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended June 30, 2012.

Incyte disclaims any intent or obligation to update these forward-looking statements.

INCYTE CORPORATION

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended <u>September 30,</u>		Nine Months Ended <u>September 30,</u>	
	2012	2011	2012	2011
Revenues:				
Product revenues, net	\$ 43,695	\$ -	\$ 92,700	\$ -
Contract revenues	16,737	16,737	90,211	65,211
Other revenues	60	45	302	354
Total revenues	<u>60,492</u>	<u>16,782</u>	<u>183,213</u>	<u>65,565</u>
Costs and expenses:				
Cost of product revenues	31	-	58	-
Research and development	50,079	44,604	150,627	126,830
Selling, general and administrative	20,520	14,282	61,634	37,067
Other expenses	-	-	-	712
Total costs and expenses	<u>70,630</u>	<u>58,886</u>	<u>212,319</u>	<u>164,609</u>
Loss from operations	(10,138)	(42,104)	(29,106)	(99,044)
Interest and other income, net	27	45	393	249
Interest expense	<u>(11,573)</u>	<u>(11,019)</u>	<u>(34,293)</u>	<u>(32,666)</u>

Loss before income taxes	(21,684)	(53,078)	(63,006)	(131,461)
Provision for income taxes	<u>26</u>	<u>-</u>	<u>93</u>	<u>-</u>
Net loss	<u>\$ (21,710)</u>	<u>\$ (53,078)</u>	<u>\$(63,099)</u>	<u>\$(131,461)</u>
Basic and diluted net loss per share	\$ (0.17)	\$ (0.42)	\$ (0.49)	\$ (1.05)
Shares used in computing basic and diluted net loss per share	130,851	126,260	129,093	125,019

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, December 31,	
	<u>2012</u>	<u>2011</u>
Cash, cash equivalents, and short-term marketable securities	\$ 243,599	\$ 277,594
Accounts receivable, net	16,540	6,415
Deferred revenue – Product revenues	-	2,332
Total assets	296,535	328,962
Convertible senior notes	315,874	298,193
Convertible subordinated notes	18,725	17,960
Total stockholders' deficit	(219,950)	(227,077)



Source: Incyte Corporation

Incyte Corporation
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