

Incyte Reports Third Quarter 2011 Financial Results and Provides Update on Key Clinical Programs

October 27, 2011

- **New Drug Application (NDA) for ruxolitinib as a treatment for myelofibrosis filed and granted priority review by the US Food and Drug Administration (FDA); PDUFA date set for December 3, 2011**
- **Commercialization activities advance; sales force recruitment completed**
- **Amendment to the Special Protocol Assessment (SPA) for RESPONSE, the Phase III trial for patients with advanced polycythemia vera, accepted by the FDA**

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

WILMINGTON, Del., Oct 27, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq: INCY) today reported third quarter financial results, provided updated information on key clinical programs and described preparations for the potential launch of ruxolitinib, an oral JAK1 and JAK2 inhibitor that is being developed as a treatment for patients with myelofibrosis (MF).

"As the FDA reviews the NDA for ruxolitinib as a potential treatment for myelofibrosis, we continue to advance our product launch preparations and have recently completed the recruitment of sixty highly qualified sales professionals with extensive prior experience in the commercialization of hematology/oncology treatments," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer.

Dr. Friedman added, "Additionally, the amendment to the SPA for RESPONSE has been accepted by the FDA. Therefore, our prior expectation regarding submission of the supplemental NDA for PV in the second half of 2013 remains unchanged."

Clinical Program Highlights:

JAK1 and JAK2 Inhibitor: ruxolitinib (also known as INCB18424 or INC424)

- The FDA accepted for filing the NDA and granted Incyte's request for priority review and has a goal to complete the review within six months. If the application is approved, Incyte anticipates that ruxolitinib could be available for US patients with MF in the fourth quarter of 2011.
- For RESPONSE, the global Phase III trial evaluating ruxolitinib in patients with advanced polycythemia vera (PV), the FDA has completed its review of our amendment to the SPA and concluded that the proposed amendment does not affect the SPA Agreement already in place.
- A randomized Phase II trial of ruxolitinib in combination with capecitabine for patients with recurrent or treatment refractory metastatic pancreatic cancer (The RECAP Trial) has been initiated and is expected to enroll 130 to 140 patients.
- An investigator-sponsored trial evaluating ruxolitinib in patients with lymphoma has recently been initiated and is expected to include approximately 90 patients.
- Multiple other 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, and a Phase I/II trial in children with hematologic malignancies and solid tumors.

JAK1 and JAK2 Inhibitor: LY3009104 (formerly known as INCB28050)

- The six-month dose-ranging Phase IIb trial in patients with rheumatoid arthritis, conducted by our collaboration partner Lilly, has completed patient enrollment.

c-MET Inhibitor: INCB28060 (also known as INC280)

- The initial Phase I trial in patients with solid tumors is ongoing and expected to continue until a maximum-tolerated or maximum-feasible dose is identified. This program is part of the Incyte-Novartis collaboration.

- The dose-escalation phase of a Phase I trial is ongoing and we expect to begin Phase II trials in patients with melanoma and ovarian cancer in 2012.

- We have discontinued further development of INCB7839 for metastatic breast cancer. This decision was based on a thorough analysis of tissue samples from over 300 breast cancer patients showing that trastuzumab based regimens are effective in the P95 positive subset of Her2 positive breast cancer.

Third Quarter 2011 Financial Results

Cash Position

As of September 30, 2011, cash, cash equivalents and marketable securities totaled \$317.0 million compared to \$424.2 million as of December 31, 2010. These amounts exclude \$28.5 million and \$37.9 million, 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 due 2015. The Company used \$138.1 million of cash during the first nine months of 2011. Excluded from this amount is \$15.9 million of proceeds from stock option exercises and a \$15 million milestone payment received from Novartis for our c-MET inhibitor, INCB28060.

Net Loss

Net loss for the quarter ended September 30, 2011 was \$53.1 million, or \$0.42 per share, as compared to net loss of \$31.7 million, or \$0.26 per share, respectively, for the same period in 2010. The net loss for the nine months ended September 30, 2011 was \$131.5 million, or \$1.05 per share, as compared to a net loss of \$64.4 million, or \$0.53 per share, for the same period in 2010.

Included in net loss for the nine months ended September 30, 2011 was a \$15 million milestone payment received from Novartis for INCB28060 as compared to a \$30 million milestone payment received from Lilly in connection with the JAK1/JAK2 inhibitor, LY3009104, and a \$3 million milestone payment from Pfizer for the CCR2 antagonist program, for the same period in 2010.

Included in net loss for the quarter and for the nine months ended September 30, 2011 were \$7.4 million and \$21.5 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$4.1 million and \$10.7 million, respectively, for the same periods in 2010.

Revenues

Total revenues for the quarter ended September 30, 2011 were \$16.8 million as compared to \$16.9 million for the same period in 2010. Total revenues for the nine months ended September 30, 2011 were \$65.6 million as compared to \$84.0 million for the same period in 2010. The decrease was primarily the result of the \$33.0 million of milestone payments from Lilly and Pfizer recognized in the nine months ended September 30, 2010, partially offset by a \$15 million milestone payment from Novartis for INCB28060 recognized in the nine months ended September 30, 2011.

Operating Expenses

Research and development expenses for the quarter and nine months ended September 30, 2011 were \$44.6 million and \$126.8 million, respectively, as compared to \$30.6 million and \$91.1 million, respectively, for the same periods last year.

Included in research and development expenses for the quarter and the nine months ended September 30, 2011 were \$4.8 million and \$14.0 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$2.6 million and \$7.3 million, respectively, for the same periods in 2010.

The increase in research and development expenses for the quarter and nine months ended September 30, 2011 was due to 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 quarter to quarter, primarily due to the timing of its clinical development activities.

Selling, general and administrative expenses for the quarter and nine months ended September 30, 2011 were \$14.3 million and \$37.1 million, respectively, as compared to \$8.5 million and \$21.6 million, respectively, for the same periods last year. Increased selling, general and administrative expenses for the quarter and nine months ended September 30, 2011 reflected the Company's preparation for the potential commercialization of ruxolitinib for MF.

Also included in selling, general and administrative expenses for the quarter and nine months ended September 30, 2011 were \$2.6 million and \$7.5 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$1.5 million and \$3.4 million, respectively, for the same periods in 2010.

Interest Expense

Interest expense for the quarter and nine months ended September 30, 2011 was \$11.0 million and \$32.7 million, respectively, as compared to \$10.5 million and \$32.7 million, respectively, for the comparable periods last year. Included in interest expense for the quarter and nine months ended September 30, 2011, was \$6.3 and \$18.4 million, respectively, of non-cash charges to amortize the discount on the Company's convertible notes, as compared to \$5.8 million and \$17.3 million, respectively, for the same periods in 2010. Interest expense for the nine months ended September 30, 2010 includes interest on the Company's 3¹/₂% convertible notes redeemed in February 2010.

Conference Call Information

Incyte will hold its third quarter 2011 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, 380549.

If you are unable to participate, a replay of the conference call will be available for thirty days. The replay dial-in number for the U.S. 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 account number 278 and the identification number 380549.

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 drug discovery and development company focused on developing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, visit the Company's web site at www.incyte.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to Incyte anticipating that ruxolitinib could be available for US patients with myelofibrosis in the fourth quarter of 2011, the expectation that submission of the supplemental NDA for ruxolitinib for PV will be made in the second half of 2013, the expectation that the randomized Phase II trial of ruxolitinib in combination with capecitabine for patients with recurrent or treatment refractory metastatic pancreatic cancer will enroll 130 to 140 patients, the expectation that the investigator-sponsored trial of ruxolitinib in patients with lymphoma will include approximately 90 patients, the expectation that the initial Phase I trial of the c-MET inhibitor INCB28060 in patients with solid tumors will continue until a maximum-tolerated or maximum-feasible dose is identified and the expectation to begin Phase II trials of the IDO inhibitor INCB24360 in patients with melanoma and ovarian cancer in 2012, are all forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the high degree of risk and uncertainty associated with drug development and clinical trials, the uncertainty associated with the regulatory approval processes, risks related to the timing of and patient enrollment in clinical trials, unanticipated developments in and risks related to the efficacy or safety of Incyte's compounds in clinical trials, the results of further research and development, risks associated with Incyte's dependence on its relationships with its collaboration partners, risks and uncertainties that may cause the parties not to achieve some or all of the commercial and developmental milestones set forth in the collaborative agreements, the risks related to market competition, changes in the timing of expenditures related to clinical development and sales and marketing activities, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2011. 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Contract revenues	\$ 16,737	\$ 16,737	\$ 65,211	\$ 83,212
License and royalty revenues	45	135	354	796
Total revenues	16,782	16,872	65,565	84,008
Costs and expenses:				
Research and development	44,604	30,609	126,830	91,106
Selling, general and administrative	14,282	8,458	37,067	21,563
Other expenses	-	(139)	712	(399)
Total costs and expenses	58,886	38,928	164,609	112,270
Loss from operations	(42,104)	(22,056)	(99,044)	(28,262)
Interest and other income, net	45	212	249	549
Interest expense	(11,019)	(10,515)	(32,666)	(32,686)
Loss on debt redemption	-	-	-	(3,988)
Loss before income taxes	(53,078)	(32,359)	(131,461)	(64,387)
Provision for income taxes	-	(658)	-	-
Net loss	\$ (53,078)	\$ (31,701)	\$ (131,461)	\$ (64,387)

Basic and diluted loss per share	\$	(0.42)	\$	(0.26)	\$	(1.05)	\$	(0.53)
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Shares used in computing basic and diluted net loss per share	126,260	122,189	125,019	121,182
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INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, <u>2011</u>	December 31, <u>2010</u>
Cash, cash equivalents, and marketable securities	\$ 316,975	\$ 424,168
Total assets	371,224	489,581
Convertible senior notes	292,566	276,445
Convertible subordinated notes	17,711	16,987
Total stockholders' deficit	(181,020)	(88,644)



SOURCE: Incyte Corporation

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