



Incyte Reports First Quarter 2011 Financial Results and Program Updates

May 3, 2011

- **Second Phase III Trial of Ruxolitinib, COMFORT-II, Conducted by Novartis, Achieved Primary Endpoint in First Quarter**
- **Ruxolitinib U.S. and E.U. Regulatory Submissions on Track for Second Quarter**
- **Data from COMFORT-I and COMFORT-II Accepted for Oral Presentations at ASCO and EHA**

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

WILMINGTON, Del., May 03, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq:INCY) today reported first quarter 2011 financial results and program updates.

"With the achievement of positive results in both pivotal Phase III trials of ruxolitinib in myelofibrosis, we and Novartis are focused on our respective regulatory filings and both companies remain on target to submit marketing applications in the second quarter," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer. "Additionally, we have received confirmation that the data from COMFORT-I and COMFORT-II will be the subject of oral presentations both at ASCO and at EHA in June."

Dr. Friedman added, "These presentations represent the first time that patients with myelofibrosis and the physicians who treat them will have the opportunity to see these robust data that demonstrate the efficacy and safety profile of ruxolitinib as compared to both placebo and best- available therapy."

Clinical Program Highlights:

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

- Positive top-line results were reported from the second pivotal Phase III registration trial, COMFORT-II, which was conducted in Europe by Novartis as part of a worldwide collaboration and license agreement with Incyte. These data demonstrate that treatment with ruxolitinib provided a statistically significant reduction in spleen size in patients with myelofibrosis (MF) when compared with best-available therapy. The safety profile of ruxolitinib was consistent with prior studies.
- The results from both COMFORT-II and the U.S. registration trial, COMFORT-I (for which positive top-line results were previously reported in December 2010) will be featured in oral presentations at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6, 2011. Data from COMFORT-I and COMFORT-II will also be featured in the 2011 Best of ASCO^(R) program.
- The COMFORT-I and COMFORT-II abstracts have been accepted for presentation at the 16th Congress of European Hematology Association (EHA) in London. The COMFORT-I abstract will be presented during the Presidential Symposium plenary session on June 11, 2011, and the COMFORT-II abstract will be the subject of an oral presentation on June 12, 2011.
- A Phase II clinical trial of ruxolitinib was initiated in patients with MF using a sustained-release formulation.
- A joint, global Phase II clinical trial was initiated with Novartis in thrombocytopenic patients with MF (specifically patients with platelet counts between 50,000 and 99,000).
- Clinical-site initiation and patient recruitment in the United States and Europe continues for the joint, global Phase III trial, RESPONSE, with Novartis, in patients with advanced polycythemia vera.

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

- Enrollment continues in the dose-ranging Phase IIb trial in rheumatoid arthritis patients conducted by our collaboration partner Lilly. The trial is expected to complete enrollment by the second half of this year.

Sheddase Inhibitor: INCB7839

- Efforts to complete the tissue analyses for the p95 assay validation are ongoing and expected to be completed mid-year.

We plan to use these results to finalize interpretation of the Phase II data in HER2-positive breast cancer patients and determine whether moving into Phase III development is warranted.

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

- The initial Phase I trial in patients with solid tumors is ongoing and expected to continue to identify the maximum-tolerated or maximum-feasible dose. A \$15 million payment from Novartis was earned during the first quarter based upon the achievement of a predefined milestone in the Phase I trial.

IDO Inhibitor: INCB24360

- The dose-escalation phase of the ongoing Phase I trial is on track and expected to be completed by year-end.

First Quarter 2011 Financial Results

Cash Position

As of March 31, 2011, cash, cash equivalents and marketable securities totaled \$383.6 million compared to \$424.2 million as of December 31, 2010. These amounts exclude \$15.0 million to be received from Novartis for the INCB28060 milestone earned and \$37.9 million of restricted cash held in an escrow account reserved for interest payments through October 2012 on the 4.75% Convertible Senior Notes due 2015. The Company used \$44.6 million of cash during the first quarter of 2011. Excluded from this amount is \$4.0 million of proceeds from stock option exercises.

Net Loss

Net loss for the quarter ended March 31, 2011 was \$26.5 million, or \$0.21 per basic and diluted share, as compared to a net loss of \$35.7 million, or \$0.30 per basic and diluted share, for the same period in 2010. Included in net loss for the quarter ended March 31, 2011 was \$15.0 million recognized under the Novartis agreement on the achievement of a predefined milestone in an ongoing Phase I dose-escalation trial for INCB28060 in patients with solid tumors. Also included in net loss for the quarter ended March 31, 2011 was \$6.9 million of non-cash expense related to the impact of expensing employee stock options, compared to \$3.1 million for the same period in 2010.

Revenues

Total revenues for the quarter ended March 31, 2011 were \$32.0 million as compared to \$17.3 million for the same period in 2010. The increase was primarily the result of the \$15.0 million predefined milestone recognized under the Novartis agreement.

As a result of the \$15 million payment to be received in connection with the aforementioned milestone from Novartis, we are increasing our revenue guidance from \$67 million to \$82 million for 2011.

Operating Expenses

Research and development expenses for the quarter ended March 31, 2011 were \$36.3 million, as compared to \$31.4 million for the same period in 2010. Included in research and development expenses for the quarter ended March 31, 2011 was a non-cash expense of \$4.4 million related to the impact of expensing employee stock options, as compared to \$2.2 million for the same period in 2010.

The increase in research and development expenses for the quarter ended March 31, 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 ended March 31, 2011 were \$10.8 million, as compared to \$5.8 million for the same period in 2010. The increase was primarily due to Company's preparation for the potential commercialization of ruxolitinib for MF and increased non-cash employee stock option expense. Included in selling, general and administrative expenses for the quarter ended March 31, 2011 was a non-cash expense of \$2.5 million related to the impact of expensing employee stock options, as compared to \$0.9 million for the same period in 2010.

Interest Expense

Interest expense for the quarter ended March 31, 2011 was \$10.8 million as compared to \$11.8 million for the same period in 2010. Included in interest expense for the quarter ended March 31, 2011, was \$6.0 million of non-cash charges to amortize the discount on the Company's convertible notes, as compared to \$6.1 million for the same period in 2010. The decrease is primarily due to interest expense incurred in 2010 on the Company's 3¹/₂% convertible notes through their redemption date in February 2010.

Conference Call Information

Incyte will hold its first quarter 2011 financial results conference call this morning at 8:30 a.m. ET. To access the conference call, please dial 877-407-8291 for domestic callers or 201-689-8345 for international callers. When prompted, provide the conference identification number, 370810.

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 370810.

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 and Novartis remaining on target to submit marketing applications for ruxolitinib in myelofibrosis in the second quarter of this year, the data from COMFORT-I and COMFORT-II being the subject of oral presentations at the 2011 American Society of Clinical Oncology meeting and the 16th Congress of European Hematology Association in June 2011 and the presentations representing the first time that patients with myelofibrosis and the physicians who treat them will have the opportunity to see data that demonstrate the efficacy of ruxolitinib as compared to both placebo and best available therapy, data from COMFORT-I and COMFORT-II also being featured in the 2011 Best of ASCO^(R) program, the expectation that the dose-ranging Phase IIb trial of LY3009104 in rheumatoid arthritis patients conducted by our collaboration partner Lilly will complete enrollment by the second half of this year, for INCB7839 the expectation that efforts to complete the tissue analyses for the p95 assay validation will be completed mid-year and our plan to use these results to finalize interpretation of the Phase II data in HER2-positive breast cancer patients and determine whether moving into Phase III development is warranted, the expectation that the initial Phase I trial of INCB28060 in patients with solid tumors will continue to identify the maximum tolerated or maximum feasible dose, the expectation that the dose-escalation phase of the initial Phase I study of INCB24360 will be completed by year-end, and financial guidance about expected revenues, 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 Annual Report on Form 10-K for the year ended December 31, 2010. 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 March 31,	
	2011	2010
Revenues:		
Contract revenues	\$ 31,738	\$ 16,737
License and royalty revenues	235	551
Total revenues	31,973	17,288
Costs and expenses:		
Research and development	36,282	31,439
Selling, general and administrative	10,825	5,794
Other expenses	691	(115)
Total costs and expenses	47,798	37,118
Loss from operations	(15,825)	(19,830)
Interest and other income (expense), net	72	195
Interest expense	(10,759)	(11,779)
Loss on debt redemption	--	(3,988)
Loss before income taxes	(26,512)	(35,402)
Provision for income taxes	--	327
Net loss	(26,512)	(35,729)
Basic and diluted net loss per share:	\$ (0.21)	\$ (0.30)
Shares used in computing basic and diluted net loss per share	123,467	119,727

INCYTE CORPORATION Condensed Consolidated Balance Sheet Data

(in thousands)

	March 31, 2011	December 31, 2010
Cash, cash equivalents, and marketable securities	\$ 383,626	\$ 424,168
Total assets	459,606	489,581
Convertible senior notes	281,694	276,445
Convertible subordinated notes	17,225	16,987
Total stockholders' deficit	(103,978)	(88,644)

SOURCE: Incyte Corporation

Incyte Corporation

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