Incyte Announces First Quarter 2004 Financial Results, Provides Update on Most Advanced Drug Discovery and Development Programs

May 4, 2004
WILMINGTON, Del.--(BUSINESS WIRE)--May 4, 2004-- Conference Call and Webcast Scheduled for Today at 8:30 a.m. ET

Incyte Corporation (Nasdaq:INCY) announced today its financial results for the first quarter ended March 31, 2004 and updated shareholders on its most recent corporate accomplishments, including:

- Presentation of positive clinical results from a 10-day Phase II dose-escalating, placebo-controlled trial designed to evaluate the antiviral effects and safety of Reverset(TM), Incyte's lead drug candidate, as monotherapy in 30 treatment-naive human immunodeficiency virus (HIV)-infected patients.
- Finalization of the protocol and site selection process for a second Phase II trial using Reverset in combination with other antiretroviral agents in 180 treatment-experienced HIV-infected individuals. Patient enrollment for this trial is currently expected to be completed by the end of 2004.
- Filing of an Investigational New Drug Application (IND) for INCB3284, Incyte's internally developed, oral CCR2 antagonist for the treatment of chronic inflammation. Patient enrollment for this first Phase I trial is expected to begin in the second quarter with results expected in the fourth quarter of 2004.
- Selection for preclinical development of a second internally developed compound, INCB7839, a novel small molecule inhibitor of sheddase, an enzyme involved in activating members of the epidermal growth factor receptor (EGFR) family. These receptors are clinically validated targets. By inhibiting sheddase, INCB7839 could block signaling mechanisms needed for the growth and metastasis of certain breast cancers, and possibly other solid tumor cancers. The company intends to file an IND for INCB7839 in the fourth quarter of 2004.
- Strengthened financial position by successfully completing the sale of $250 million 3-1/2% convertible subordinated notes due 2011, in a private placement to qualified institutional buyers. The notes are convertible into shares of Incyte common stock at approximately $11.22 per share, a 35% premium to the price of Incyte common stock on February 12, 2004, the date that the notes were priced for sale. Incyte may redeem the notes beginning February 20, 2007.
- Closure of its Palo Alto, California facilities effective April 2, 2004, thus completing the final step in its transition to a drug discovery and development company. Through the closure of its Palo Alto facilities, Incyte expects to eliminate up to $50 million in annual costs.

First Quarter 2004 Financial Highlights:

Cash Position: As of March 31, 2004, cash and short-term investments totaled approximately $501 million compared to $294 million as of December 31, 2003. The increase is a result of the sale of $250 million of the company's 3- 1/2 % convertible subordinated notes, which resulted in net proceeds of approximately $242 million, partially offset by the company's cash use of approximately $35 million. In line with prior guidance, the company expects to use between $130 and $140 million in cash in 2004, excluding any possible in-license or purchase of products in clinical development, or any debt repurchases.

Net Loss: The total net loss for the first quarter of 2004 was $37.7 million, or $0.52 per share, compared to $55.8 million, or $0.81 per share, for the same period in 2003. Included in Incyte's first quarter 2004 net loss were restructuring and related charges of $7.6 million in connection with the closure of its facilities in Palo Alto. The company expects to record up to an additional $40 million of restructuring and related charges in the second quarter of 2004. The total expected 2004 restructuring charge of up to $47 million is unchanged from our previous guidance. Also included in the company's net loss for the first quarter of 2004 is a charge of $2.7 million as a result of write-downs related to reduced market valuations in strategic investments that Incyte holds in other companies. This charge is included in interest income and other income/expense, net. Included in the first quarter 2003 net loss was a charge of $28.1 million for purchased in-process research and development expense related to the acquisition of Maxia Pharmaceuticals, Inc.

Revenues: Revenues for the quarter ended March 31, 2004 were $6.6 million compared to revenues of $12.5 million for the same period in 2003. The decrease in revenues, which were primarily derived from the company's information products, reflects the company's decision to discontinue its Palo Alto-based information products line.

Expenses: Total research and development expense was $26.2 million in the first quarter of 2004 compared to $30.2 million for the same period of 2003. The decreased expense is a result of the company's cost cutting and restructuring efforts at its Palo Alto facilities, which was partially offset by increased expenses associated with our drug discovery and development programs. Selling, general and administrative expenses were $6.3 million in the first quarter of 2004 compared to $7.4 million for the same period as last year.

David Hastings, executive vice president and CFO of Incyte stated, "During the first quarter of 2004, Incyte successfully continued its focus on rationalizing the company's infrastructure and significantly strengthening its cash position in order to better position the company to execute its drug discovery and development strategy."

Drug Discovery and Development Update

Reverset: Reverset is an investigational nucleoside-analogue reverse transcriptase inhibitor (NRTI) that is being developed as a once-a-day oral therapy for use in combination with other antiviral drugs for patients with HIV infections.

On February 11, Incyte and Pharmasset, Inc., its strategic collaborative and licensing partner for Reverset, announced that Phase II results presented at the 11th Annual Conference on Retroviruses and Opportunistic Infections demonstrated that Reverset achieved potent antiviral effects in treatment-naive HIV patients. In this Phase II trial, which was designed to evaluate the antiviral effects and safety of Reverset as monotherapy, the mean reduction in viral load for all treated patients ranged from 1.67 log10 copies/mL to 1.77 log10 copies/mL. The study involved three, once-a-day, dose levels: 50 mg, 100 mg and 200 mg, and demonstrated that Reverset was well-tolerated at all doses over the 10-day trial period.

A second Phase II trial using Reverset in combination with other antiviral agents in 180 treatment-experienced HIV-infected individuals is expected to begin in the first half of 2004. If results from the second Phase II trial are positive, Incyte currently expects to begin two pivotal Phase III studies in mid 2005.

CCR2 Receptor Antagonist Program: Incyte filed the IND for INCB3284 on April 6, 2004 and expects to begin a single center, single and multiple dose Phase I study this quarter. The primary objective of the Phase I trial is to evaluate the tolerability as well as the pharmacokinetic and pharmacodynamic effects of INCB3284 in healthy volunteers. The study will include a surrogate pharmacological "proof-of-principle" endpoint that is intended to confirm the anti-inflammatory potential of INCB3284 in humans.

A growing body of preclinical and clinical data suggests that CCR2 receptors play a central role in the establishment and maintenance of chronic inflammatory processes. CCR2 and its primary ligand, MCP-1, represent a critical signaling pathway responsible for the recruitment of peripheral blood monocytes to sites of immune-mediated inflammation, where they become inflammatory macrophages. As the severity of inflammation in a number of disease states, including rheumatoid arthritis, multiple sclerosis and neuropathic pain, correlates with the number of macrophages in tissue, Incyte believes CCR2 receptor antagonists have the potential to be developed as anti-inflammatory therapies in multiple indications. Given the broad potential of this new class of compounds, Incyte intends to form a strategic partnership with a pharmaceutical company with strong development and commercialization capabilities in relevant therapeutic areas.

Paul A. Friedman, M.D., Incyte's CEO, stated, "We have moved the CCR2 program from concept to IND-stage in only two years. I believe the rapid progress which led to this first IND, along with our selection of a second preclinical candidate from our sheddase inhibitor program, demonstrates the strength, experience and talent of our drug discovery and development team."

Sheddase Inhibitor Program: Incyte's scientists have identified a number of novel, potent and orally available small molecule inhibitors of sheddase; these have shown efficacy in multiple animal tumor models both as single agents and in combination with other cancer therapies. A lead compound in this program, INCB7839, was nominated for development during the first quarter and is currently undergoing preclinical toxicology testing to support an IND filing in the fourth quarter of 2004.

Dr. Friedman stated, "Our sheddase inhibitors interfere with activation of members of the epidermal growth factor receptor (EGFR) family - clinically relevant receptors targeted by Herceptin(R), Erbitux(R), Iressa(R) and Tarceva(R). Inhibition of signaling by the EGFR-family pathways has been shown to be effective in the treatment of multiple tumor types, including breast cancer, non-small cell lung cancer and colorectal cancer. By acting at a distinct step in the EGFR pathways, our sheddase inhibitors offer the potential to shut down these pathways more completely. Given the clear need for safer and more effective cancer therapies, we look forward to seeing this compound move forward into clinical testing."

Early Stage Discovery Programs: In addition to these three drug discovery and development programs, Incyte has a number of earlier-stage discovery efforts in cancer and diabetes. As these compounds advance closer to lead optimization and preclinical testing, the company intends to provide greater detail on the potential utility and value of these earlier stage programs. In parallel with its internal discovery efforts, Incyte is continuing to seek compounds in early clinical development or late preclinical testing that may be available for in-licensing from other companies.

Conference Call Information

Incyte will host a conference call on Tuesday May 4, 2004 at 8:30 a.m. ET to discuss the news contained in this release. The domestic dial in number is 1-877-692-2592 and the international dial in number is 1-973-582-2700. The conference ID # is 4474069.

If you are unable to participate, a replay of the conference call will be available through May 30, 2004 (12:00 midnight ET). The replay dial-in number for the U.S. is 877-519-4471 and dial-in number for international callers is 973-341-3080. The replay pin number is 4734865.

About Incyte

Incyte is a Wilmington, Delaware-based drug discovery and development company with a growing pipeline of novel small molecule drugs to treat HIV, inflammation, cancer and diabetes. The company's most advanced product candidate, Reverset, is an oral, once-a-day therapy in Phase II clinical trials to treat patients with HIV infections. Currently, Incyte has four drug discovery programs underway and a proteomic information business based in Beverly, Massachusetts.

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements as to Incyte's expected reduction in annual operating expenses associated with this restructuring, its ability to focus on its drug discovery and development activities, plans to move Reverset through a second Phase II trial by the end of 2004 and plans to move Reverset through Phase III during 2005, the expected utility of Incyte's CCR2 compounds as anti-inflammatory therapies in multiple indications, plans to begin a Phase I in the first half of 2004 for Incyte's lead orally available, small molecule CCR2 compound and expected Phase I results in the fourth quarter of 2004, plans to form a strategic partnership for the CCR2 compounds, the expected utility of a novel protease inhibitor alone or in combination with other therapies in treating breast cancer and other solid cancers, plans to enter its lead sheddase inhibitor compound into human testing in the fourth quarter of 2004, Incyte's strengthened cash position, the expected cash impact in 2004 from restructuring related charges, and financial guidance as to expected cash utilization in 2004, 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 results of further research, the impact of competition and of technological advances and the ability of Incyte to compete against parties with greater financial or other resources,

unanticipated delays, unanticipated cash requirements and the ability to raise additional capital, the ability to implement technological improvements, diversion of management attention in implementing the announced restructuring plans and associated transition risks, unanticipated costs or delays associated with closing the company's California facilities, unexpected attrition in the company's Delaware and Massachusetts facilities, Incyte's ability to obtain regulatory approval for its products or to conduct clinical trials for its product candidates, its ability to enroll a sufficient number of patients for its clinical trials and its ability to obtain effective patent protection for its discoveries and to continue to be effective in expanding its patent coverage, and other risks detailed from time to time in Incyte's Annual Report on Form 10-K for the year ended December 31, 2003 and other filings with the Securities Exchange Commission. Incyte assumes no obligation and expressly disclaims any duty to update the information contained in this presentation.

Financial Statements Follow

Incyte Corporation
Condensed Consolidated Balance Sheet Data
(in thousands)

	Three Months Ended	
	March 31, 2004	March 31, 2003
Revenues	$6,641	$12,509
Operating expenses:		
Research and development	26,184	30,186
Selling, general and administrative	6,292	7,377
Purchased in-process research and development	-	28,116
Other expenses	7,642	1,103
Total operating expenses	40,118	66,782
Loss from operations	(33,477)	(54,273)
Interest and other income (expense), net	(413)	1,233
Interest expense	(3,520)	(2,439)
Gain/(loss) on certain derivative financial instruments	(177)	(45)
Provision for income taxes	(128)	(260)
Net loss	$(37,715)	$(55,784)
Basic and diluted net loss per share	$(0.52)	$(0.81)
Shares used in computing basic and diluted net loss per share	72,643	68,986

Incyte Corporation
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2004	December 31, 2003
Cash, cash equivalents & marketable securities	$500,707	$293,807
Total assets	$582,468	$379,545
Convertible subordinated notes	$417,682	$167,786
Total stockholders' equity	$117,818	$154,333

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SOURCE: Incyte Corporation