Lilly and Incyte Announce Collaboration for Development and Commercialization of Oral Anti-Inflammatory and Autoimmune Therapies

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Lilly Gains Worldwide Rights for Incyte's Novel JAK1/JAK2 Inhibitor, INCB28050, for Inflammatory and Autoimmune DiseasesIncyte to Receive $90 Million Upfront Payment and up to $665 Million in Potential Milestones, Plus Royalties on Future Sales; Incyte Retains Co-Development & Co-Promotion Options

INDIANAPOLIS and WILMINGTON, Del., Dec 21, 2009 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (Nasdaq: INCY) announced today that they have entered into an exclusive worldwide license and collaboration agreement for the development and commercialization of Incyte's oral JAK1/JAK2 inhibitor, INCB28050, and certain follow on compounds, for inflammatory and autoimmune diseases. The lead compound, INCB28050, is currently being studied in a six-month dose-ranging Phase II trial for rheumatoid arthritis.

Under the terms of the agreement, Lilly will receive worldwide rights to develop and commercialize INCB28050 as an oral treatment for all inflammatory conditions. In exchange for these rights, Incyte will receive an initial payment of $90 million and is eligible for up to $665 million in additional potential development, regulatory, and commercialization milestones, as well as tiered, double-digit royalty payments on future global sales with rates ranging up to twenty percent if a product is successfully commercialized.

"This new alliance with Incyte reinforces Lilly's commitment to expand our presence in inflammation and autoimmunity through the development of a new class of oral anti-inflammatory therapies," said Eiry Roberts, M.D. Lilly vice president for autoimmune product development. "We look forward to continuing the development of INCB28050 in RA and initiating additional clinical studies to help address the unmet patient needs from debilitating autoimmune and inflammatory diseases."

Paul Friedman, Incyte's president and chief executive officer, stated, "Lilly's success in bringing novel therapies to market, their commitment to building a franchise in inflammation and autoimmunity, and their enthusiasm regarding the potential of JAK inhibition gives us confidence that the full therapeutic and commercial potential of INCB28050 in RA as well as other autoimmune and inflammatory conditions can be rapidly and effectively achieved through this agreement. This collaboration leverages the capabilities and strengths of each partner and achieves our objective to retain significant value for Incyte's shareholders."

Incyte will retain the option to co-develop its JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis beginning at the initiation of Phase IIb development. Under the agreement, if Incyte elects to co-develop any compounds and/or indications, Incyte would be responsible for funding thirty percent of the associated future global development costs from the initiation of a Phase IIb trial. Incyte would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global sales for compounds and/or indications that Incyte elects to co-develop. Incyte expects that the earliest it would consider exercising a co-development option would be in the second half of 2010, concurrent with the potential initiation of a Phase IIb trial with INCB28050.

Development of the JAK1/JAK2 inhibitors will be governed by a joint development committee. Incyte also has the option to co-promote products in the US.

As a result of this transaction, Lilly expects to incur a charge to earnings in the fourth quarter of 2009 of approximately $.05 per share. The company reconfirmed its full-year 2009 earnings-per-share guidance of $3.90 to $4.00 per share on a reported basis, or $4.30 to $4.40 per share on a pro forma non-GAAP basis.

About Rheumatoid Arthritis (RA)

Rheumatoid arthritis is an autoimmune disease, estimated to affect about 1% of the world's population. The disease is characterized by aberrant immune mechanisms that lead to joint inflammation and swelling with progressive destruction of joints. In addition to affecting the joints, RA can affect connective tissue in the skin and organs of the body. Current treatments include the non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs such as methotrexate, and the newer injectable biological response modifiers that target tumor necrosis factor alpha, a pro-inflammatory cytokine implicated in the pathogenesis of rheumatoid arthritis. None of these treatments is curative and RA remains a disease for which there is still a significant unmet clinical need.

About JAK Inhibition

There are four known JAK enzymes: JAK1, 2, 3 and TYK2. These enzymes are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in RA patients. Cytokines such as interleukin-6, -12, and -23 signal through the JAK pathway and have been clinically validated as therapeutic targets in inflammatory diseases. Additional JAK-dependent cytokines have also been implicated in a number of inflammatory and autoimmune diseases suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions.

About INCB28050

INCB28050 is an orally-available, potent and selective JAK1/JAK2 inhibitor that is currently in Phase II development as a treatment for RA. In previously conducted Phase II studies, Incyte's JAK1/JAK2 inhibitors have demonstrated efficacy and have been well tolerated in clinical studies to date.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology, inflammation and diabetes. Incyte's most advanced compound, INCB18424, is in Phase III development for myelofibrosis. For additional information on Incyte, visit the Company's web site at www.incyte.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. C-LLY

Lilly Safe Harbor Statement

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products (including the compounds discussed in this press release) that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; the rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; business development transactions; changes in tax law; asset impairments and restructuring charges and the impact of exchange rates. For additional information about the factors that affect the company's business, please see the company's latest Form 10-K, filed February 2009, and Form 10-Q filed October 2009. The company undertakes no duty to update forward-looking statements.

Incyte Safe Harbor Statement

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to with respect to the potential for Incyte to receive up to $665 million in additional potential milestones, Incyte's expectation for the earliest time for it to consider exercising a co-development option, Incyte's confidence that the full therapeutic and commercial potential of INCB28050 in RA as well as other inflammatory conditions can be rapidly and effectively achieved through the collaboration agreement, and the potential for JAK inhibitors to be useful for the treatment of a broad range of inflammatory conditions, 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 the parties not to achieve some or all of the commercial and developmental milestones set forth in the collaboration agreement and that may otherwise cause Incyte's actual results and timing 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, risks related to the potential failure of INCB28050 to demonstrate safety and efficacy in clinical testing, risks and uncertainty associated with the therapeutic and commercial value of INCB28050, risks relating to Lilly's and Incyte's abilities to successfully develop and commercialize drug candidates, risks relating to market competition, risks associated with Incyte's dependence on its relationship with its collaboration partners, 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 September 30, 2009. Incyte disclaims any intent or obligation to update these forward-looking statements.

SOURCE Eli Lilly and Company; Incyte Corporation