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Lilly Discontinues Phase 3 Rheumatoid Arthritis Program for Tabalumab Based on Efficacy Results

Decision not based on safety concerns; Phase 3 lupus program continues as planned

INDIANAPOLIS, Feb. 7, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) announced today that it will discontinue the Phase 3 rheumatoid arthritis (RA) program for tabalumab, an anti-BAFF (B cell activating factor) monoclonal antibody, due to lack of efficacy. The decision was not based on safety concerns. The tabalumab Phase 3 program for systemic lupus erythematosus, ILLUMINATE, is ongoing and will continue as planned.

In December 2012, Lilly discontinued the Phase 3 RA registration study FLEX-M for lack of treatment effect. FLEX-M was investigating tabalumab in patients with moderate-to-severe RA who had an inadequate response to methotrexate therapy.

Based on FLEX-M findings, an interim futility analysis was conducted of the FLEX-V study, which was investigating tabalumab for the treatment of patients with moderate-to-severe RA who had an inadequate response to one or more tumor necrosis factor (TNF) inhibitors.

Based on the outcomes of these two separate interim futility analyses, Lilly has decided to discontinue development of tabalumab in the current RA program. All ongoing Phase 2 and Phase 3 RA studies will be stopped.

"While we are obviously disappointed by these results in rheumatoid arthritis, we continue to believe that tabalumab could have significant potential for patients in other disease areas," said Eiry Roberts, M.D., vice president of autoimmune product development at Lilly. "Autoimmune disorders are highly individualized. We believe that targeting BAFF with a molecule such as tabalumab may still represent an important advance for patients, and therefore we will continue the ongoing Phase 3 tabalumab lupus program."

The decision to stop the current RA program for tabalumab is expected to result in a first-quarter charge to research and development expense of approximately $50 million. The company's previously issued financial guidance for 2013 remains unchanged.

About the FLEX-V Study
The FLEX-V study (study BCDV) is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of tabalumab in patients with moderate-to-severe RA who had an inadequate response to one or more TNF inhibitors.

About BAFF and Tabalumab
BAFF (B cell activating factor) is a cytokine that promotes B cell survival, proliferation and activation. In the presence of excess BAFF, B cells, including autoreactive B cells, are not appropriately eliminated by the immune system and may therefore contribute to the development of RA by producing autoantibodies and proinflammatory cytokines and "helping" autoreactive T cells. BAFF exists in both membrane-bound and soluble forms. Tabalumab is a human immunoglobulin G subclass 4 (IgG4) monoclonal antibody (MAb) that inhibits both membrane-bound and soluble B cell activating factor (BAFF). Tabalumab is currently in Phase 3 development as a potential treatment for systemic lupus erythematosus and in Phase 2 development in combination with bortezomib for patients with previously-treated multiple myeloma.

About Lilly's Autoimmune Pipeline
Tabalumab is one of three potential new medicines in late-stage clinical development for a variety of autoimmune conditions. The others are ixekizumab, an anti-IL-17 monoclonal antibody, for psoriasis and psoriatic arthritis; and baricitinib, a JAK1 and JAK2 inhibitor being developed in collaboration with Incyte Corporation, for RA, psoriasis and diabetic nephropathy.

About Lilly's Pipeline
Lilly currently has a number of unique potential medicines in its Phase 3 clinical development pipeline, representing a variety of therapeutic areas including diabetes (four), cancer (three), neuroscience (two), autoimmunity (three) and cardiovascular (one). To learn more about the molecules in Lilly's clinical development pipeline, please visit Lilly's interactive pipeline website available at www.lilly.com/pipeline.

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.

This press release contains forward-looking statements about the potential of tabalumab for the treatment of rheumatoid arthritis and lupus, and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the compound will receive regulatory approval, or that it will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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