



October 2, 2014

Lilly to Discontinue Development of Tabalumab Based on Efficacy Results in Phase 3 Lupus Studies

INDIANAPOLIS, Oct. 2, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will discontinue development of tabalumab -- being studied for the treatment of systemic lupus erythematosus (SLE, commonly known as lupus) -- due to insufficient efficacy in two pivotal Phase 3 trials. The decision was not based on safety concerns.

In the ILLUMINATE 1 study, tabalumab did not achieve the primary endpoint, at either dose studied, of statistically significant improvement on SRI-5 (SLE Responder Index-5, a measurement of lupus disease activity and response), compared to standard of care therapy. In ILLUMINATE 2, the higher dose of tabalumab met this endpoint, the first time a lupus study has achieved this efficacy measure as a primary endpoint in a Phase 3 trial. Collectively, the data from these studies did not meet expectations for efficacy in the context of existing treatments. The overall safety profile showed a similar frequency of adverse events in patients treated with either tabalumab or standard of care. Lilly intends to submit these data for disclosure in appropriate upcoming scientific venues.

Given the overall efficacy results from these two pivotal Phase 3 studies, Lilly will not move forward with submissions to global regulators. Lilly will work with investigators to appropriately conclude these studies in the interest of patient safety.

"Although we were pleased that tabalumab met the criteria for statistically significant improvement in the SRI-5 endpoint in one of our trials, we are nonetheless disappointed that the overall results did not meaningfully improve the condition of the patients in these studies," said J. Anthony Ware, M.D., Senior Vice President, Product Development, Lilly Bio-Medicines. "The ILLUMINATE trials are the largest Phase 3 clinical studies in lupus to date, and we are hopeful that our contribution of the extensive data from these studies will advance knowledge to enhance treatment in this devastating illness. Lilly remains committed to developing potential new medicines for the treatment of autoimmune conditions, including lupus."

The decision to discontinue development of tabalumab for lupus is expected to result in a third-quarter charge to research and development expense of up to \$75 million (pretax), or approximately \$0.04 - \$0.05 per share (after-tax).

About systemic lupus erythematosus (SLE)

Systemic lupus erythematosus (also known as lupus) is a chronic, autoimmune disease that can damage any part of the body (skin, joints, and/or organs inside the body), and can range from mild to life-threatening. The Lupus Foundation of America estimates that up to 1.5 million people in the United States and 5 million people throughout the world have a form of lupus. Lupus strikes mostly women of childbearing age (15-44), though men, children, and teenagers also develop lupus. Most people develop lupus between the ages of 15-44.¹

About Eli Lilly and Company (NYSE: LLY)

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>.

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This press release contains forward-looking statements about tabalumab as a potential treatment for systemic lupus erythematosus and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. 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.

¹ Lupus Foundation of America: <http://www.lupus.org/answers/entry/what-is-lupus> (Accessed September 29, 2014)

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