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Lilly Announces Pomaglumetad Methionil Did Not Meet Primary Endpoint of Clinical Study

Development of the molecule continues based on observed safety profile, additional data anticipated later in 2012

INDIANAPOLIS, July 11, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today negative clinical trial results from study H8Y-MC-HBBM (HBBM) investigating pomaglumetad methionil, also known as mGlu2/3, for the treatment of patients suffering an acute exacerbation of schizophrenia. In study HBBM, pomaglumetad methionil did not separate from placebo in the primary efficacy endpoint in either the overall or predefined genetic subpopulation (based on the Positive and Negative Syndrome Scale, PANSS) at the two doses investigated (40 mg and 80 mg BID). The active control, risperidone, did separate from placebo in both populations. Pomaglumetad methionil was generally well tolerated in this study, with no new safety findings compared to previous trials. Data will be shared at a later date at an appropriate scientific venue.

HBBM was intended to be the first of two clinical trials to support registration of the compound for monotherapy in acute schizophrenia. The second registration clinical trial, H8Y-MC-HBBN (HBBN), is ongoing. The company will conduct an interim analysis of study HBBN which will provide results later in the year. Additionally, Lilly awaits results from the recently concluded study H8Y-MC-HBCO (HBCO). HBCO is a Phase II study exploring pomaglumetad methionil as an adjunctive treatment with atypical antipsychotics. Data from these two studies will help inform decisions on the future development of pomaglumetad methionil. Ongoing clinical trials with pomaglumetad methionil continue.

"Unfortunately negative studies are common in the field of psychiatry and a reality of biopharmaceutical innovation," said Jan Lundberg, Ph.D., executive vice president, science and technology, and president, Lilly Research Laboratories. "Despite all of the advances, the need for new and better treatments for those suffering with mental illnesses is among the most urgent in medicine. Lilly has long been a pioneer in neuroscience, and we're committed to discovering and delivering breakthrough treatments that make a difference for patients. Right now, we're developing more than a half dozen potential new medicines to treat neuroscience-related diseases and disorders, including among others, depression, Alzheimers disease and schizophrenia."

About Pomaglumetad Methionil

Pomaglumetad Methionil (mGlu2/3) is a glutamatergic-based agent that, unlike all currently available antipsychotic drugs, does not interact with those central nervous system receptors that are thought to be responsible for many of the intolerable adverse events (e.g., motor dysfunction, reproductive hormone irregularity, weight gain, lipid elevation) associated with present schizophrenia treatments.

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.

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This press release contains forward-looking statements about the potential of LY2140023 monohydrate for the treatment of schizophrenia, 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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