Lilly Announces Inconclusive Phase II Study Results for mGlu2/3 at the International Congress on Schizophrenia Research

--Development of the molecule continues following a positive proof-of-concept study published in the 2007 journal Nature Medicine

SAN DIEGO, March 29, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today inconclusive Phase II clinical trial results from Study HBBI investigating LY2140023 monohydrate, also known as mGlu2/3, for the treatment of patients suffering from acute schizophrenia. In Study HBBI, neither LY2140023 monohydrate, nor the comparator molecule olanzapine, known to be more effective than placebo, separated from placebo. In this particular study, Lilly observed a greater-than-expected placebo response, which was approximately double that historically seen in schizophrenia clinical trials.

Because inconclusive clinical trial results are common in the field of neuroscience and given the previous positive proof-of-concept study for this compound, Study HBBD, which was published in the September 2007 issue of the journal Nature Medicine, Lilly is continuing with the development of LY2140023 monohydrate. Lilly plans an additional Phase II study, Study HBBM, which if positive, would validate the HBBD proof-of-concept trial results.

Six hundred sixty nine patients enrolled in Study HBBI and 393 completed this four-week, in-patient trial. A higher-than-expected placebo response was observed (14.6 points improvement) as measured by the Positive and Negative Syndrome Scale (PANSS) total score. The primary analyses did not demonstrate that any of the four LY2140023 monohydrate doses (5, 20, 40 and 80 mg taken twice daily) separated from placebo. Similarly, olanzapine at 15mg once daily also did not separate from placebo. LY2140023 monohydrate was generally well- tolerated, although convulsions were observed in three patients. Furthermore, LY2140023 monohydrate had a low association with adverse events commonly associated with currently available antipsychotics and showed no appreciable weight gain.

Steven Paul, M.D., executive vice president, science and technology, and president, Lilly Research Laboratories, said, "All currently prescribed antipsychotics act on dopamine receptors. Lilly remains optimistic that the novel mechanism of compounds with the ability to reduce glutamate hyperactivity, such as our mGlu2/3 receptor agonist, will someday represent the next generation of breakthrough treatments for schizophrenia."

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class 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 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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