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Lilly Announces FDA Requirement of Additional Clinical Trial Before Ruboxistaurin Could Be Approved for Treatment of Diabetic Retinopathy

Additional Trial Would Take Up To Five Years to Complete; Lilly Currently Evaluating Options

INDIANAPOLIS, Sept 29, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company today announced that it is weighing options for the further development of ruboxistaurin mesylate in light of a request by the Food and Drug Administration (FDA) for an additional, three-year, Phase 3 clinical trial. The FDA said it wants additional efficacy data before it will consider approving the molecule for the treatment of moderate to severe nonproliferative diabetic retinopathy. Lilly believes that such a trial would require up to five years to complete. Today's announcement follows Lilly's August 18, 2006, announcement that it had received an approvable letter from the FDA.

"We are certainly disappointed with this communication from the FDA. Diabetic retinopathy is a significant unmet medical need to which we have devoted more than a decade of clinical research with no guarantee of approval," said Dr. John Lechleiter, president and chief operating officer of Eli Lilly and Company. "We still believe that ruboxistaurin has potential as a treatment for diabetic eye disease and are exploring the feasibility of further development of this molecule," he added.

Ongoing clinical trials for ruboxistaurin will continue while Lilly evaluates its options for further development of ruboxistaurin.

Ruboxistaurin (proposed brand name Arxxant(TM), pronounced ark-ZONT) was submitted to the FDA in February 2006 and subsequently was granted priority review. The August 17 approvable letter from the FDA requested additional efficacy data to support the clinical evidence presented by Lilly in its New Drug Application (NDA). Today's announcement results from ongoing communication between Lilly and the FDA to determine if the additional evidence could come from ongoing trials or if a new trial would be required.

At this time, Lilly does not intend to withdraw the NDA, because withdrawal would require restarting the review process, should Lilly ultimately move forward with development of ruboxistaurin.

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.

This press release contains forward-looking statements about the potential of ruboxistaurin, an investigational compound for the treatment of moderate to severe nonproliferative diabetic retinopathy and reflects Lilly's current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the product will receive regulatory approvals, or that the regulatory approval will be for the indication(s) anticipated by the company. 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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