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Eli Lilly and Company Announces Approvable Letter Issued by FDA for Arxxant(TM) (ruboxistaurin mesylate)

INDIANAPOLIS, Aug 18, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company announced today that it received an approvable letter from the U.S. Food and Drug Administration (FDA) for ruboxistaurin mesylate (proposed trade name Arxxant(TM), pronounced, ark-ZONT), its investigational oral therapy being studied for treatment of diabetic retinopathy (DR), a diabetic eye disease.

In its letter, the FDA has requested submission of additional data to support the clinical evidence presented by Lilly in its new drug application (NDA). Lilly plans to meet with the FDA to determine whether this request can be satisfied with data from an ongoing study or whether a new study is required.

"We will be working closely with the FDA to address issues outlined in the approvable letter and to define the pathway forward," said Dr. Timothy R. Franson, Vice President of Global Regulatory Affairs, Eli Lilly and Company.

About Arxxant

Arxxant is an investigational therapy for the treatment of moderate to severe non-proliferative diabetic retinopathy. It works by limiting the overactivation of protein kinase C beta (PKC b), a naturally occurring enzyme that has been linked to the development of diabetic retinopathy. It is the first of a new class of compounds being investigated for the treatment of moderate to severe non-proliferative diabetic retinopathy.

Lilly submitted a new drug application (NDA) to seek approval from the U.S. Food and Drug Administration for ruboxistaurin for the treatment of moderate to severe non-proliferative diabetic retinopathy in February 2006.

About Diabetic Retinopathy

Diabetic retinopathy (DR) occurs when diabetes damages the small blood vessels in the retina, a part of the eye that is needed for vision. This damage can lead to vision loss and possible blindness. DR affects an estimated 4.1 million Americans age 40 and older with 899,000 having a vision-threatening form of the disease,(1) and it is the leading cause of blindness among working-age adults.(2)

Lilly's Leadership in Diabetes

Through a long-standing commitment to diabetes care, Lilly provides patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been the industry leader in pioneering therapies to help health care professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients.

About Lilly

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 the investigational compound ruboxistaurin for the treatment of 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. There is also no guarantee that the product will prove to 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. P-LLY

(1) Kempen, et al.: The Prevalence of Diabetic Retinopathy Among Adults in the United States. Arch Ophthalmol, 122:552-563 (2004).

(2) Fong, et al.: Retinopathy in Diabetes. Diabetes Care, 27:584-587 (2004)

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SOURCE Eli Lilly and Company

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