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Eli Lilly and Company and Boehringer Ingelheim Announce Changes to Their Contractual Agreements for Yentreve® AriClaim®

Feb 15, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company and Boehringer Ingelheim announced today that the alliance will change the nature of its contractual agreements for Yentreve®/AriClaim® (duloxetine hydrochloride), a pharmaceutical treatment for stress urinary incontinence (SUI), which is currently approved for marketing in 38 countries outside of the United States.

Lilly will repurchase sole worldwide commercialization rights to Yentreve/AriClaim (duloxetine for SUI and future related urinary incontinence indications) and will continue marketing this indication outside the U.S. The Lilly-Boehringer Ingelheim agreement to market duloxetine outside the U.S. for major depressive disorder (MDD), diabetic peripheral neuropathic pain (DPNP) and other potential indications (under the trademarks Cymbalta®/Xeristar®) remains unaffected by today's announcement.

"Based on our collective experiences to date in the marketplace, both companies believe that the Yentreve/AriClaim opportunity is best suited and can be best commercialized in markets outside the U.S. with the support of one company," said John Lechleiter, Ph.D., president and chief operating officer of Lilly. "This is about 'right sizing' our investments to address our greatest opportunities and the greatest patient needs."

"There has been an excellent spirit of collaboration in our alliance with Lilly. Based on this, we are committed to the continued success in our partnership to commercialize duloxetine for indications other than SUI in markets outside the U.S.," said Dr. Alessandro Banchi, chairman of the Board of Managing Directors at Boehringer Ingelheim.

Additionally, the alliance has determined it will not seek marketing authorization for Yentreve in the U.S. following its decision to rescind the initial new drug application in January 2005.

"The decision not to pursue approval for Yentreve in the U.S. was a difficult one given the belief both companies share about the importance of SUI as a medical condition and Yentreve's proven ability to address a significant unmet medical need," Lechleiter stated.

"Collectively, these business decisions will ensure focused resources in markets where Yentreve is already approved and aggressive investments in newer areas of duloxetine's development and commercialization that relate to depression and pain. We are very optimistic about our ability to build on the achievements we have experienced in our alliance with Boehringer Ingelheim," he added.

Both parties are finalizing the terms of the agreement and will work closely together in 2006 to ensure a smooth transition of all related activities to Lilly. Lilly plans to take over full commercialization of Yentreve/AriClaim in markets outside the U.S. by the end of 2006.

Lilly and Boehringer Ingelheim will continue to market Cymbalta/Xeristar outside the U.S. for major depressive disorder and diabetic peripheral neuropathic pain, and to develop potential new indications including generalized anxiety disorder and fibromyalgia. Lilly owns the rights to commercialize Cymbalta in the United States.

About AriClaim and Xeristar

In Greece, Italy and Spain, the contractual agreement for duloxetine for stress urinary incontinence allowed the product to be available under the trade names Yentreve (marketed by Lilly) and AriClaim (marketed by Boehringer Ingelheim). Similarly, duloxetine for depression and diabetic peripheral neuropathic pain (MDD and DPNP) in Greece, Italy and Spain will continue to be available as Cymbalta (marketed by Lilly) and Xeristar (marketed by Boehringer Ingelheim).

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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 on www.lilly.com. LLY-P

About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 144 affiliates in 45 countries and nearly 36,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2004, Boehringer Ingelheim posted net sales of 8.2 billion euro while spending nearly one fifth of net sales in its largest business segment Prescription Medicines on research and development. Additional information about Boehringer Ingelheim is available on www.boehringer-ingelheim.com.

<http://www.newscom.com/cgi-bin/prnh/20040122/BILOGO>)

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