



Priligy™ (Dapoxetine) Receives First Regulatory Approvals for the Treatment of Premature Ejaculation (PE) in Finland and Sweden

Priligy First Oral Prescription Medication Approved for PE

Beerse, Belgium, 10 February, 2009 - Janssen-Cilag EMEA, a division of Janssen Pharmaceutica N. V., announced today that Priligy™ (dapoxetine) has received marketing authorisation in Finland and Sweden for the on-demand treatment of premature ejaculation (PE) in men 18-64 years of age. These approvals follow the positive outcome of a decentralised marketing authorisation procedure in seven European Union countries: Sweden, Austria, Finland, Germany, Spain, Italy and Portugal. The procedure was finalised in December 2008, and Finland and Sweden are the first countries worldwide to grant marketing authorisation for this compound. National approvals and licenses in the other five European countries are expected to follow. Dapoxetine is not approved for marketing in the United States.

Dapoxetine is a drug specifically developed for the on-demand treatment of PE and is the first oral medication (tablet) to be approved for this condition. Dapoxetine has been extensively evaluated in five randomised, placebo-controlled Phase III clinical trials involving more than 6,000 men with PE and their partners. This is the largest and most comprehensive clinical trial programme to date for a drug therapy to treat PE. Dapoxetine is a unique, short-acting, selective serotonin reuptake inhibitor (SSRI) designed to be taken only when needed, that is 1-3 hours before sexual intercourse is anticipated, rather than every day.

Dapoxetine will be marketed by Janssen-Cilag, marking another significant advance in the company's commitment to developing innovative, high quality treatments for unmet medical needs.

Premature Ejaculation

PE is a distressing sexual dysfunction that can be present from the first sexual encounter or can develop later in life. Depending on the methodology and criteria used to evaluate the prevalence of PE in studies, the reported proportion of men affected with this condition at some point in their lives has ranged from 4-30%. Experts in PE from the International Society of Sexual Medicine (ISSM) define the condition as consisting of three major components: a short time to ejaculation (prior to or within about one minute), lack of ejaculatory control and negative personal impact or distress related to ejaculation. Unlike erectile dysfunction (ED), which tends to affect older men, PE has similar prevalence across all age groups. In fact, more men are believed to experience PE than ED.

A combination of physiological and psychological factors are believed to influence the mechanism of ejaculation. Men with PE appear to go through the same process of ejaculation as other men, but it happens more quickly and with a reduced feeling of control. Research suggests serotonin plays a central role in the timing of ejaculation.

About dapoxetine

ALZA Corporation, a Janssen-Cilag affiliate, licensed dapoxetine from PPD-GenuPro in 2001 with exclusive worldwide rights to develop and commercialise the compound for urogenital therapies, including premature ejaculation.

The clinical trial programme for the use of dapoxetine in premature ejaculation was conducted by Johnson & Johnson Pharmaceutical Research and Development. The product will be marketed by Janssen-Cilag in most countries where regulatory approval has been granted.

Product Availability

After approval in a specific country, Priligy (dapoxetine) will only be available by prescription from a healthcare professional.

The product is expected to be made available for purchase in licensed pharmacies in the countries where approved around April 2009, after all local regulatory requirements related to packaging and pricing are finalised. Janssen-Cilag will provide official confirmation of the exact date of product availability in each individual country. Applications for marketing authorisation in other countries are under review.

Unapproved imitations (counterfeit) of dapoxetine have been sold. Government officials from around the world have warned of the potential risks associated with counterfeit drugs, including the risk of death. As for any prescription medication, patients should buy Priligy (dapoxetine) only from a pharmacy that is officially licensed by government authorities. Patients should be especially cautious of internet pharmacies, as many of these are unlicensed.

About Janssen-Cilag

The Janssen-Cilag companies are part of the Johnson & Johnson family of companies. They have a long track record in developing and marketing treatments for central nervous system disorders, pain management, oncology, infectious diseases, reproductive health and gastrointestinal disorders. More information about Janssen-Cilag can be found at www.janssen-cilag.com.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) J&JPRD is part of the Johnson & Johnson family of companies. J&JPRD is headquartered in Raritan, NJ, and has facilities throughout Asia, Europe and the United States. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas to address unmet medical needs worldwide.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from Janssen-Cilag's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Janssen-Cilag does not undertake to update any forward-looking statements as a result of new information or future events or developments.)

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