

Astellas Pharma Inc.: Submits Application for Marketing Approval of Degarelix, an GnRH Antagonist for Prostate Cancer Treatment, in Japan

Tokyo, October 28, 2010 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced today that it submitted a market authorization application for one month formulation of degarelix acetate (“degarelix”; generic name; development code: ASP3550) to the Ministry of Health, Labour and Welfare in Japan. Astellas is seeking an approval for the indication of prostate cancer.

Degarelix is a gonadotrophin-releasing hormone (GnRH) blocker with a subcutaneously injectable formulation. GnRH is a hormone produced in the hypothalamus in the brain and is involved in the production of the male hormone testosterone through binding to the GnRH receptors in the pituitary gland. Although testosterone is an important hormone that plays a central role in the maintenance of male function, it also stimulates prostate cancer to grow and to spread out and in result, often aggravates symptoms in prostate cancer patients. Degarelix competitively inhibits the binding of GnRH to the GnRH receptors and controls the growth of prostate cancer by suppressing the testosterone production. The Phase II study in Japan demonstrated the maintenance of blood testosterone below castration level for one year. Also, based on the safety results, degarelix appears to be safe and well tolerated. Based on the results of Phase-I and Phase-II studies in Japan, Astellas decided to submit this market authorization application by using abroad Phase-III data, skipping Phase III study in Japan.

Degarelix was approved for the treatment of prostate cancer by the U.S. Food and Drug Administration (FDA) in December 2008, and by the European Medicines Agency (EMA) in February 2009, and is commercialized in twenty-one countries* including U.S., Canada, U.K., Germany, and France.

In January 2006, Astellas and Ferring International Center SA (“Ferring”; headquarters: Saint-Prex, Switzerland; Chairman: Frederik Paulsen) entered into a license agreement that gives Astellas exclusive rights to develop and market degarelix for the treatment of prostate cancer in Japan. Since then, Astellas has conducted the development of degarelix in Japan from Phase II. Upon this application for marketing approval in Japan, Astellas will pay to Ferring the milestone payment of €10 million, which was reflected in Astellas’ current fiscal year (from April 1, 2010 to March 31, 2011) financial forecast.

Astellas expects to provide an additional therapeutic option, and further contribute to the treatment of prostate cancer by introducing degarelix with a new mechanism of action, into the Japanese market. Also, Astellas puts a high strategic focus on the urology therapeutic area, commercializing a treatment for overactive bladder Vesicare[®] and a treatment for functional symptoms of benign prostate hyperplasia Harnal[®] and believes the degarelix’ application for marketing approval in Japan is an important step to expand our business and reinforce Astellas’ presence and commitment in the area of urology, as well as a bridgehead of the entry into the area of oncology, Astellas’ third prioritized area alongside urology and transplant, in Japan

*as of August 17, 2010

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