

Press Release

Astellas Submits a New Drug Application for Gonax[®] 12-Week Extended-Release Formulation for Treatment of Prostate Cancer in Japan

Tokyo, November 30, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced that that it submitted an application for marketing approval in Japan of GnRH antagonist, Gonax[®] (development code: ASP3550; generic name: degarelix acetate) 12-week extended-release formulation for treatment of prostate cancer.

Gonax[®] became available in 4-week extended-release formulation with the indication of prostate cancer in October 2012 in Japan. The 12-week extended-release formulation is expected to improve convenience of use and increase adherence for patients.

Astellas sets that Oncology is one of focused disease areas for research and development, and expects that Gonax[®] 12-week extended-release formulation will further expand the treatment choices available for patients with prostate cancer.

Submission of the application for marketing approval has no impact on the financial results for the fiscal year 2017 ending March 31, 2018.

About Gonax[®]

Gonax[®] is a gonadotrophin-releasing hormone (GnRH) antagonist with a subcutaneously injectable formulation. Astellas acquired exclusive development and commercialization rights of Gonax[®] for the use of prostate cancer treatment in Japan from Ferring International Center SA* in January 2006. GnRH is a hormone synthesized and released from 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. Gonax[®] competitively inhibits the binding of GnRH to the GnRH receptors and controls the growth of prostate cancer by suppressing the testosterone.

*All rights and obligations under the agreement were assigned by Ferring International Center SA to Ferring Private Ltd. in January 2016.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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