

## **Astellas Obtains Approval in Japan for Treating Prostate Cancer with Gonax<sup>®</sup> for Subcutaneous Injection**

Tokyo, June 29, 2012 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced that Gonax<sup>®</sup> for Subcutaneous Injection (development code: ASP3550, generic name: Degarelix Acetate, “Gonax”) was granted Japanese marketing approval today for the indication of prostate cancer.

Gonax 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. Gonax competitively inhibits the binding of GnRH to the GnRH receptors and controls the growth of prostate cancer by suppressing the testosterone production. Based on the results of Phase I and Phase II studies in Japan, Astellas decided to submit the market authorization application by using abroad Phase-III data.

In Phase II studies in Japan and the abroad Phase III studies, Gonax suppressed and maintained the blood testosterone below castration at Day 3, without a testosterone surge which frequently occurs with GnRH agonist treatment. Also, based on the safety results, Gonax appears to be safe and well tolerated.

Gonax has been approved in 59 countries.

In January 2006, Astellas and Ferring Pharmaceuticals (“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 Gonax in Japan from Phase II. Upon this 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, 2012 to March 31, 2013) financial forecast.

Astellas Pharma expects to provide an additional therapeutic option in treating prostate cancer by introducing Gonax into the Japanese market.

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PRODUCT SUMMARY

Product name: Gonax<sup>®</sup> 80mg /120mg for Subcutaneous Injection

Generic name: Degarelix Acetate

Indication: Prostate Cancer

Dosage regimen The usual starting dose of Degarelix for adults is 240mg given as two subcutaneous injections of 120mg. After 4 weeks from the initial dose, the maintenance dose of Degarelix is 80mg given as one subcutaneous injection, every 4 weeks.

Starting Dose: per an injection point, reconstitute a vial containing 120mg Degarelix with 3ml of Japanese Pharmacopoeia Sterile Water for Injections and inject subcutaneously immediately after reconstitution (at a concentration of 40mg/ml)

Maintenance Dose: reconstitute a vial containing 80mg Degarelix with 4.2ml of Japanese Pharmacopoeia Sterile Water for Injections and inject subcutaneously immediately after reconstitution (at a concentration of 20mg/ml)

For inquiries or additional information
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