Astellas Launches Gonax® (Degarelix Acetate) for Subcutaneous Injection in Japan for Treating Prostate Cancer

Tokyo, October 22, 2012 - Astellas Pharma Inc. ("Astellas"; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced the launch of Gonax® for Subcutaneous Injection (development code: ASP3550, generic name: Degarelix Acetate, "Gonax") in Japan for the indication of prostate cancer on October 23, 2012.

Gonax is a gonadotrophin-releasing hormone (GnRH)-receptor blocker with a subcutaneously injectable formulation. GnRH is a hormone produced by 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 abroad Phase-III data in addition to the results of Phase I and Phase II studies in Japan, Astellas decided to submit the market authorization application.

In Phase II studies in Japan and the abroad Phase III studies, Gonax suppressed and maintained the blood testosterone below castration from Day 3 and during the whole treatment period, 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 62 countries to date.

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 and submitted the market authorization application in Japan. Subsequently, Gonax was granted Japanese marketing approval on June 29, 2012 and listed on the NHI price listing on August 28, 2012.

Upon the launch of Gonax, Astellas will not revise its financial forecast for the current fiscal year (from April 1, 2012 to March 31, 2013).

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

###

*The product name outside Japan is marketed under Firmagon®

Product Summary

Product name:	Gonax® 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)
Package:	Gonax® 80mg for Subcutaneous Injection: 1 vial Gonax® 120mg for Subcutaneous Injection: 2 vials
Drug Price:	Gonax® 80mg for Subcutaneous Injection 1 vial: ¥23,693 Gonax® 120mg for Subcutaneous Injection 1 vial: ¥29,126
Drug price listing date:	28 August, 2012
Launch date:	23 October, 2012 (Plan)

Image of Package and Vial

For inquiries or additional information
Astellas Pharma Inc. Corporate Communications TEL: +81-3-3244-3201, FAX:+81-3-5201-7473 http://www.astellas.com/en