Press Release

Astellas Announces Approval in Japan for the treatment of prostate cancer, Gonax® for partial changes (addition of dosage and administration) and addition of Gonax® 240 mg

TOKYO, January 8, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that gonadotrophin-releasing hormone (GnRH) receptor antagonist, Gonax® received approval for partial changes for the additional dosage and administration of Gonax® for the treatment of prostate cancer at 12-week intervals, and obtained manufacturing and marketing authorization for Gonax® 240 mg in Japan.

Gonax® is a GnRH receptor 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 Pharmaceuticals in January 2006, and launched Gonax® for the indication of prostate cancer in Japan in October 2012.

GnRH is a hormone synthesized and released from the hypothalamus in the brain and is involved in the production of the male hormone testosterone thorough 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.

Astellas believes that adding the maintenance dose of Gonax® 480 mg at 12-week intervals to the maintenance dose of Gonax® 80 mg at 4-week intervals will improve convenience for patients and reduce the burden on patients and further contribute to the treatment of prostate cancer.

Astellas reflected the impact from this approval in its financial forecasts of the current fiscal year ending March 31, 2019.

Product overview

Trade name	Gonax® 80 mg for Subcutaneous Injection, Gonax® 120 mg for Subcutaneous Injection, and Gonax® 240 mg for Subcutaneous Injection
Generic name	Degarelix acetate
Indication	Prostate cancer
Dosage and administration (with additional underlined areas)	Usually in adults, the starting-dose as degarelix is 240 mg which is administered as two subcutaneous injections of 120 mg each in two different abdominal regions. The second and subsequent doses of degarelix are administered at a maintenance-dose, starting four weeks after the starting-dose. For patients treated with every-four-week repeated doses, degarelix is administered at a maintenance-dose of 80 mg as one subcutaneous injection in one abdominal region. For patients treated with every-twelve-week repeated doses, degarelix is administered at a maintenance-dose of 480 mg as two subcutaneous injections of 240 mg each in two different abdominal regions. Starting-Dose: Add 3.0 mL of (JP) Water for Injection into a 120 mg vial of this product for one injection site. Administer one vial of this product immediately after reconstitution as a subcutaneous injection of 3.0 mL in the abdominal region. (Dissolution with 3.0 mL of water results in a drug concentration of 40 mg/mL.) Every-four-week, Maintenance-dose Treatment: Add 4.2 mL of (JP) Water for Injection into an 80 mg vial of this product. Administer one vial of this product immediately after reconstitution as a subcutaneous injection of 4.0 mL in the abdominal region. (Dissolution with 4.2 mL of water results in a drug concentration of 20 mg/mL.) Every-twelve-week, Maintenance-dose Treatment: Add 4.2 mL of (JP) Water for Injection into a 240 mg vial of this product for one injection site. Administer one vial of this product immediately after reconstitution as a subcutaneous injection of 4.0 mL in the abdominal region. (Dissolution with 4.2 mL of water results in a drug concentration of 60 mg/mL.)
Date of approval	January 8, 2019

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. 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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