Astellas Receives Approval for XTANDI Tablets, a Treatment for Castration-Resistant Prostate Cancer, in Japan

Tokyo, March 1, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced that 40 mg XTANDI Tablets and 80 mg XTANDI Tablets received manufacturing and marketing approval in Japan for the treatment of castration-resistant prostate cancer, which add additional dosage forms to the previously available 40 mg XTANDI Capsules. XTANDI (generic name enzalutamide) is an oral androgen receptor inhibitor.

Both the 40 mg XTANDI Tablets and 80 mg XTANDI Tablets are smaller in size than the 40 mg XTANDI Capsules; thus offering a more patient-friendly medication. With the 80 mg tablets, the number of tablets taken each time will also be reduced.

Enzalutamide as of January 2018, was being sold in more than 70 countries worldwide. In Japan, XTANDI Capsules were launched in May 2014 for castration-resistant prostate cancer.

Astellas is pleased to deliver XTANDI tablets to patients to further enhance its contributions to the treatment of castration-resistant prostate cancer in the future.

The approval will have no effect on company results in the current fiscal year (ending March 2018).
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.

About the Pfizer/Astellas Collaboration
In October 2009, Medivation, Inc., which is now part of Pfizer (NYSE:PFE), and Astellas (TSE: 4503) entered into a global agreement to jointly develop and commercialize enzalutamide. The companies jointly commercialize XTANDI in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.

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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