Press Release

XTANDI® (enzalutamide soft capsules) Approved by China NMPA for the Treatment of Non-Metastatic Castration-Resistant Prostate Cancer

Enzalutamide is now NMPA-approved for both non-metastatic and metastatic castration-resistant prostate cancer

TOKYO, November 6, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that the China National Medical Products Administration (NMPA) has approved XTANDI® (enzalutamide soft capsules) for the treatment of adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) with high risk of metastasis. This is the second approved indication in China for enzalutamide, which is already available for adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT), in whom chemotherapy is not yet indicated.

The approval is based on results from the PROSPER trial, a double-blind, placebo-controlled, pivotal Phase 3 trial that evaluated enzalutamide plus ADT versus placebo plus ADT in 1,401 men with nmCRPC and rapidly rising prostate-specific antigen levels. PROSPER met its primary endpoint of metastasis-free survival (MFS), with a median MFS of 36.6 months for men who received enzalutamide plus ADT, compared to 14.7 months with placebo plus ADT. Results demonstrated a 71 percent reduction in the risk of radiographic progression or death in men who received enzalutamide plus ADT, compared to placebo plus ADT (hazard ratio=0.29 [95% confidence interval: 0.24-0.35]; p<0.001).

The most common adverse events of any grade for patients ≥10% and higher for enzalutamide plus ADT vs. placebo plus ADT were: fatigue (33% vs. 14%), hot flush (13% vs. 8%), hypertension (12% vs. 5%), nausea (11% vs. 9%), fall (11% vs. 4%), dizziness (10% vs. 4%) and decreased appetite (10% vs. 4%). These results were published in the *New England Journal of Medicine* in 2018. Results from the study's overall survival secondary endpoint were published in the *New England Journal of Medicine* in 2020.

"In order to maintain quality of life for men with non-metastatic prostate cancer, new treatments are needed to delay the progression of prostate cancer and prevent it from spreading to other areas in the body. In clinical studies, enzalutamide significantly reduced the risk of the cancer spreading or death compared to placebo alone," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas.

“Enzalutamide in non-metastatic castration-resistant prostate cancer provides patients and their doctors with an important new option for the treatment of their advancing prostate cancer,” said Hiroshi Hamaguchi, President, Greater China Commercial, Astellas. “We look forward to serving more patients and physicians as we expand our work in prostate cancer and continue to grow the Astellas oncology program in China.”

Astellas reflected the impact from this approval in its financial forecast of the current fiscal year ending March 31, 2021.

About Non-Metastatic Castration-Resistant Prostate Cancer
In China, prostate cancer is the most common tumor in male urology-related cancers.[1] It is the second most common cancer in men worldwide.[2]

Castration-resistant prostate cancer (CRPC) refers to the subset of men whose prostate cancer progresses on androgen deprivation therapy (ADT) despite castrate levels of testosterone (i.e., less than 50 ng/dL).[3] Non-metastatic CRPC means there is no clinically detectable evidence of the cancer spreading to other parts of the body (metastases), and there is a rising prostate-specific antigen (PSA) level.[4] Many men with non-metastatic CRPC and a rapidly rising PSA level go on to develop metastatic CRPC.[5]

About the PROSPER trial
The Phase 3 randomized, double-blind, placebo-controlled, multi-national trial enrolled approximately 1,400 patients with non-metastatic castration-resistant prostate cancer (CRPC) at sites in the United States, Canada, Europe, South America and the Asia-Pacific region. PROSPER enrolled patients with prostate cancer that had progressed, based on a rising PSA level despite ADT, but who had no symptoms and no prior or present evidence of metastatic disease. The trial evaluated enzalutamide at a dose of 160 mg taken orally once daily plus ADT, versus placebo plus ADT.

The primary endpoint of the PROSPER trial, MFS, is a measure of the amount of time that passes until a cancer can be radiographically detected as having metastasized, or until death, within 112 days of treatment discontinuation. Secondary endpoints included time to PSA progression, time to first use of antineoplastic therapy and overall survival.

For more information on the PROSPER trial, go to www.clinicaltrials.gov.

About XTANDI® (enzalutamide soft capsules)
Enzalutamide is an androgen receptor signaling inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and non-metastatic castration-resistant prostate cancer (nmCRPC).[6]

Important Safety Information
For Important Safety Information for enzalutamide please see the Package Insert.

About Astellas
Astellas Pharma Inc., is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions combining our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands 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 enzalutamide in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing enzalutamide 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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