Press Release

China's National Medical Products Administration Accepts New Drug Application for XTANDI® (enzalutamide) in Metastatic Hormone-Sensitive Prostate Cancer

TOKYO, September 19, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted its New Drug Application (NDA) for XTANDI® (enzalutamide) for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC).

Ahsan Arozullah, M.D., MPH, Senior Vice President and Head of Oncology Development, Astellas
"With a median survival of only three to four years from starting androgen deprivation therapy, patients with metastatic hormone-sensitive prostate cancer in China are in need of new treatment options. We look forward to working with the CDE to advance this NDA, which represents the third application acceptance for XTANDI in advanced prostate cancer in China."

The NDA is based on results from the Phase 3 China ARCHES study. In the study, 180 Chinese patients with mHSPC in mainland China were randomized to receive XTANDI plus androgen deprivation therapy (ADT) or placebo plus ADT. The study met its primary endpoint, demonstrating a statistically significant improvement in time to prostate-specific antigen (PSA) progression (TTPP), defined as a ≥ 25% increase and an absolute increase of ≥ 2 µg/L (2 ng/mL) above the nadir (i.e., lowest PSA value observed post baseline or at baseline), which is confirmed by a second consecutive value at least 3 weeks later. These topline findings also showed consistent results with those in Astellas' global Phase 3 ARCHES study in the same target population.[7]

In China ARCHES, the safety of XTANDI plus ADT was broadly consistent with the known safety profile for the medication.

Results from China ARCHES will be presented in a poster presentation during the European Society of Medical Oncology (ESMO) Congress 2023.

XTANDI has not been approved by the NMPA for the treatment of mHSPC.

Astellas has already reflected the impact from this acceptance in its financial forecast of the current fiscal year ending March 31, 2024.

About Metastatic Hormone-Sensitive Prostate Cancer
In China, prostate cancer is the most common tumor in male genitourinary cancers.[1] It is the second most common cancer in men worldwide.[2] Prostate cancer is considered metastatic once it has spread outside of the prostate gland to other parts of the body, such as distant lymph nodes, bones, lungs, and liver.[3] Men are considered hormone- (or castration-) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels.[4] Metastatic hormone-sensitive prostate cancer (mHSPC) has a median survival of approximately 3-4 years for men starting treatment with ADT.[5]

About the China ARCHES Trial

The company-sponsored, multicenter, Phase 3, randomized, double-blind, placebo-controlled China ARCHES trial (NCT04076059) enrolled 180 Chinese patients with metastatic hormone-sensitive prostate cancer (mHSPC) across 30 sites in mainland China. Patients in the trial were randomized to receive XTANDI 160 mg daily or placebo and continued on a luteinizing hormone-releasing hormone (LHRH) agonist or antagonist or had a history of bilateral orchiectomy. The primary endpoint of the trial was time to prostate-specific antigen (PSA) progression (TTPP), defined as a ≥ 25% increase and an absolute increase of ≥ 2 ng/mL above the nadir, which is confirmed by a second consecutive value at least 3 weeks later. Secondary endpoints include radiographic progression-free survival (rPFS), time to first Symptomatic Skeletal Event (SSE), time to castration resistance, PSA response (≥ 50%), PSA response (≥ 90%), time to initiation of new antineoplastic therapy, PSA undetectable rate, which is defined as the percentage of subjects with detectable (≥ 0.2 ng/mL) PSA at baseline, which becomes undetectable (< 0.2 ng/mL) during study treatment, and objective response rate (ORR).

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

About XTANDI® (enzalutamide soft capsules)
Enzalutamide is an androgen receptor signaling inhibitor indicated for the treatment of adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) with high-risk of metastasis or metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy is not yet clinically indicated.[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 that combine 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 commercial agreement to jointly develop and commercialize XTANDI® (enzalutamide) in the United States, while Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing the product 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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