Press Release

China's National Medical Products Administration Approves XTANDI® (enzalutamide) in Metastatic Hormone-Sensitive Prostate Cancer

- Approval marks XTANDI's third indication for advanced prostate cancer in China -
- Approval based on positive results from Phase 3 global ARCHES and China ARCHES studies showing XTANDI plus androgen deprivation therapy (ADT) significantly delays time to PSA progression compared to placebo plus ADT -

TOKYO, July 2, 2024 – 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 approved XTANDI® (enzalutamide) for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC).

The approval is based on positive results from the Phase 3 global ARCHES and China ARCHES studies. China ARCHES used a surrogate endpoint (time to PSA progression) to bridge to the global ARCHES study results. In the China ARCHES study, 180 Chinese patients with mHSPC in mainland China were randomized to receive XTANDI plus ADT or placebo plus ADT. Results show XTANDI plus ADT significantly reduced the risk of PSA progression by 87% vs placebo plus ADT (HR 0.130 [95%CI 0.076,0.222]; P<0.0001). Radiographic progression free survival (rPFS), time to castration resistance (TTCR), and PSA undetectable rate were among the secondary endpoints improved with XTANDI in combination with ADT compared to placebo plus ADT. These findings again show consistent positive results for XTANDI in line with those in Astellas' global Phase 3 ARCHES study. In China ARCHES, the safety of XTANDI plus ADT was consistent with the known safety profile for the medication. Overall, these findings support the earlier usage of XTANDI in this treatment setting.[1,2]

Professor Dingwei Ye, Principal Expert of Prostate Cancer, Fudan University-affiliated Cancer Hospital:
"Prostate cancer is the most common tumor in male genitourinary cancers in China. Currently, the mortality-to-incidence ratio of prostate cancer in China is higher than that in developed countries. In addition to further improving the disease diagnosis rate of prostate cancer, there is an urgent clinical need for new treatment options that can slow the progression of the disease while further enhancing the overall survival for Chinese patients."

Prof. Zhou Fangjian, Principal Expert of Prostate Cancer, Sun Yat-sen University Cancer Center, Sun Yat-sen University:
"With the approval of the mHSPC indication, enzalutamide has become the only novel hormone therapy drug that covers chemotherapy naïve mCRPC, nmCRPC and mHSPC, providing strong support to the comprehensive disease management for the vast number of advanced Chinese prostate cancer patients. Most importantly, the China ARCHES study is currently the only Phase 3 clinical trial conducted specifically for Chinese patients, and its results have provided definitive clinical evidence for Chinese clinicians in the treatment of advanced prostate cancer."

Ahsan Arozullah, MD, MPH, Senior Vice President and Head of Oncology Development, Astellas:
"We now have compelling, consistent efficacy data for XTANDI in mHSPC across three large Phase 3 trials – ENZAMET, global ARCHES and China ARCHES which have supported approvals around the world. Astellas is deeply committed to bringing XTANDI to those who need it. This approval by the NMPA expands access to a much-needed treatment option for those facing advanced prostate cancer in China."

Astellas has already reflected the impact from this approval for XTANDI in China in its financial forecast for the current fiscal year ending March 31, 2025.

For more information, please see the press releases "China's National Medical Products Administration Accepts New Drug Application for XTANDI® (enzalutamide) in Metastatic Hormone-Sensitive Prostate Cancer" issued on September 19, 2023, and "Astellas Announces Phase 3 China ARCHES Study of XTANDI® Meets Primary Endpoint" issued on March 14, 2023.

About Metastatic Hormone-Sensitive Prostate Cancer
In China, prostate cancer is the most common tumor in male genitourinary cancers.[3] It is the second most common cancer in men worldwide.[4] 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.[5] Men are considered hormone- (or castration-) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels.[6] Metastatic hormone-sensitive prostate cancer (mHSPC) has a median survival of approximately 3-4 years for men starting treatment with ADT.[7]

About global ARCHES
The Phase 3, randomized, double-blind, placebo-controlled, multi-national trial enrolled 1,150 patients with metastatic hormone-sensitive prostate cancer (mHSPC) at sites in the United States, Canada, Europe, South America and the Asia-Pacific region. Patients in the ARCHES 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 ARCHES trial included patients with both low- and high-volume disease and both newly diagnosed patients with mHSPC and patients who had prior definitive therapy and subsequently developed metastatic disease. The trial also included some patients who had received recent treatment with docetaxel for mHSPC, but whose disease had not progressed. The primary endpoint of the trial was radiographic progression-free survival (rPFS), defined as the time from randomization to the first objective evidence of radiographic disease progression as assessed by central review, or death within 24 weeks of treatment discontinuation.

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

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)
XTANDI (enzalutamide) is an androgen receptor signaling [or signaling] inhibitor. XTANDI is a standard of care and has received regulatory approvals in one or more countries around the world for use in men with metastatic hormone-sensitive prostate cancer (mHSPC), metastatic castration-resistant prostate cancer (mCRPC), non-metastatic castration-resistant prostate cancer (nmCRPC) and non-metastatic hormone-sensitive prostate cancer (nmHSPC) with high-risk biochemical recurrence (BCR). XTANDI is currently approved for one or more of these indications in more than 90 countries, including in the United States, European Union and Japan. Over one million patients have been treated with XTANDI globally.[8]

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.

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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