Press Release

Astellas Submits Supplemental New Drug Application for Approval of Additional Indication of XTANDI® for the Treatment of Men with Metastatic Hormone-Sensitive Prostate Cancer in Japan

TOKYO, July 30, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that it has submitted a supplemental new drug application for the oral androgen receptor signaling inhibitor XTANDI® (generic name: enzalutamide, "XTANDI") to add the indication for the treatment of men with metastatic hormone-sensitive prostate cancer (mHSPC) in Japan. XTANDI is currently indicated for the treatment of men castration-resistant prostate cancer (CRPC) in Japan.

The submission is based on results from the Phase 3 ARCHES trial presented at the 2019 Genitourinary Cancers Symposium (ASCO GU) in February and published in The Journal of Clinical Oncology. The study evaluated the efficacy and safety of XTANDI plus androgen deprivation therapy (ADT) versus ADT plus placebo in men with mHSPC. The primary endpoint of radiographic progression-free survival (rPFS) was met in the study.

Additionally, the submission is supported by data from ENZAMET, an Astellas-supported, investigator-sponsored Phase 3 research study led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and sponsored by the University of Sydney. The ENZAMET trial evaluated XTANDI plus ADT versus ADT plus a standard nonsteroidal antiandrogen therapy (bicalutamide, nilutamide or flutamide) in men with mHSPC to provide an active control. The results were presented during the Plenary Session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June and simultaneously published in the New England Journal of Medicine. The primary endpoint of overall survival (OS) was met in the ENZAMET trial. The safety analysis of the ARCHES and ENZAMET trials appear consistent with the safety profile of enzalutamide in previous clinical trials in CRPC.

Enzalutamide is currently indicated for the treatment of CRPC in the U.S. and Europe. Data from the ARCHES and ENZAMET studies have also been submitted to the European Medicines Agency (EMA) and to the U.S. Food & Drug Administration (FDA) to potentially support an indication for XTANDI that includes men with mHSPC.

About ARCHES

The Phase 3, randomised, double-blind, placebo-controlled, multi-national trial enrolled 1,150 patients with mHSPC at sites in the United States, Canada, Europe, South America and the Asia-Pacific region. Patients in the ARCHES trial were randomised to receive enzalutamide 160 mg daily or placebo and continued on a luteinising 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 randomisation to the first objective evidence of radiographic disease progression as assessed by central review, or death within 24 weeks of treatment discontinuation.[i] For more information on the ARCHES (NCT02677896) trial, go to www.clinicaltrials.gov.

About ENZAMET

ENZAMET is a trial sponsored by the University of Sydney with trial sites in Australia, Canada, Ireland, New Zealand, UK and United States. The trial evaluates the potential of enzalutamide plus androgen deprivation therapy (ADT) versus a conventional non-steroidal anti androgen (NSAA) plus ADT in 1,125 men with mHSPC. The primary endpoint for the trial is overall survival (OS).[ii] Additional details about ENZAMET (NCT02446405) are available on www.clinicaltrials.gov. Astellas provided funding and support for the ENZAMET trial.

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

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 commercialise enzalutamide. The companies jointly commercialise enzalutamide in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercialising 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.

###

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473

---

[i] Clinicaltrials.gov. A Study of Enzalutamide Plus Androgen Deprivation Therapy (ADT) Versus Placebo Plus ADT in Patients With Metastatic Hormone Sensitive Prostate Cancer (mHSPC) (ARCHES). Available at: https://clinicaltrials.gov/ct2/show/NCT02677896. Last accessed June 2019.

[ii] Clinicaltrials.gov. Enzalutamide in First Line Androgen Deprivation Therapy for Metastatic Prostate Cancer (ENZAMET). Available at: https://clinicaltrials.gov/ct2/show/NCT02446405?cond=ENZAMET&rank=1. Last accessed June 2019.