Press Release

European Medicines Agency Accepts Type II Variation Application Filing for XTANDI™ (enzalutamide) In Non-Metastatic Castration-resistant Prostate Cancer

TOKYO – March 16, 2018 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced today that the European Medicines Agency (EMA) has validated and started the review process for Astellas' application for a Type II Variation for enzalutamide to extend the overall indication to include patients with non-metastatic castration-resistant prostate cancer (CRPC) based on results from the Phase 3 PROSPER trial.

"In many cases, men see their prostate cancer progress after initial androgen deprivation therapy. Until recently, no treatments have been proven efficacious for men with unproven metastatic disease castration-resistant prostate cancer," said Dr Cora N. Sternberg, a key investigator in the trial and Chief of Medical Oncology at San Camillo Forlanini Hospital, Italy. "The PROSPER data may help us better understand this challenging stage of the disease."

Astellas announced first results for the PROSPER trial at the 2018 Genitourinary Cancers Symposium in February. Additional data from the PROSPER trial, including prostate-specific antigen (PSA) response rates and patient-reported outcome measures, will be presented at the upcoming 2018 European Association of Urology in Copenhagen.

About PROSPER

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 prostate-specific antigen (PSA) level despite androgen deprivation therapy (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, metastasis-free survival (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. Some 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 Prostate Cancer

Prostate cancer is the second most common cancer in men worldwide.[1] More than 164,000 men in the United States are estimated to be newly diagnosed with prostate

cancer in 2018.[2] In the European Union, the estimated number of new prostate cancer cases in 2015 was 365,000.[3]

Castration-resistant prostate cancer (CRPC) refers to the subset of men whose prostate cancer progresses despite castration levels of testosterone.[4] 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.[5] Many men with non-metastatic CRPC and a rapidly rising PSA level go on to develop metastatic CRPC.[6]

About Enzalutamide
Enzalutamide was first approved by the European Commission in June 2013 for the treatment of adult men with metastatic castration-resistent prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy. Enzalutamide is also approved in Europe for the treatment of adult men with mCRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

Important Safety Information for Enzalutamide
For important Safety Information for enzalutamide please see the full Summary of Product Characteristics at: https://www.medicines.org.uk/emc/product/3203.

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 prioritised 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 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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[1] American Cancer Society. Global Cancer Facts and Figures (2015). https://www.cancer.org/content/dam/cancerorg/research/cancer-factsand-statistics/global-cancerfacts-and-figures/globalcancer-facts-and-figures-3rdedition.pdf. Accessed 01-11-2018.
[2] American Cancer Society. Key Statistics for Prostate Cancer. https://www.cancer.org/cancer/prostate-cancer/about/keystatistics.html. Accessed 01-08-2018.
[3] European Commission. Epidemiology of prostate cancer in Europe (03-17-2017). https://ec.europa.eu/jrc/en/publication/epidemiology-prostate-cancereurope. Accessed 01-19-2018.
[4] Kirby M, Hirst C, Crawford ED. Characterising the castration resistant prostate cancer population: a systematic review. *Int J Clin Pract* 2011;65(11):1180-92.
[5] Luo J, Beer T, Graff J. Treatment of nonmetastatic castration-resistant prostate cancer. *Oncology* 2016;30(4):336-44.
[6] Smith MR, Kabbinavar F, Saad F, Hussain A et al. Natural history of rising serum prostate-specific antigen in men with castrate nonmetastatic prostate cancer. *J Clin Oncol* 2005;23:2918–2925.