

Press Release

Astellas' XTANDI™ (enzalutamide) Approved by European Commission for Men with Metastatic Hormone-Sensitive Prostate Cancer

Enzalutamide is now the only oral therapy approved by the European Commission to treat three distinct types of advanced prostate cancer

TOKYO, May 4, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) announced today that the European Commission (EC) has approved an additional indication for the oral once-daily therapy XTANDI™ (enzalutamide) for adult men with metastatic hormone-sensitive prostate cancer (mHSPC, also known as metastatic castration-sensitive prostate cancer or mCSPC). Men diagnosed with mHSPC tend to have a poor prognosis, with a median survival of approximately 3-4 years,¹ underscoring the need for new treatment options.

With this indication, enzalutamide is now the only oral treatment approved by the EC to treat three distinct types of advanced prostate cancer — non-metastatic and metastatic castration-resistant prostate cancer (CRPC) and mHSPC.² The EC approval is based on results from the pivotal Phase 3 ARCHES trial which evaluated enzalutamide in men with mHSPC.³

“Metastatic hormone-sensitive prostate cancer patients have limited options and, unfortunately, there is a poor prognosis for many men,” said Andrew Armstrong, M.D., Professor of Medicine, Surgery, Pharmacology and Cancer Biology, Director of Research in the Duke Cancer Institute’s Center for Prostate and Urologic Cancers and lead investigator of ARCHES. “The research supporting this approval provides clinical evidence showing how enzalutamide can help improve outcomes for men with mHSPC, which gives healthcare professionals in Europe the option to offer the treatment across the advanced prostate cancer disease continuum.”

Data from the ARCHES trial showed enzalutamide plus androgen deprivation therapy (ADT) significantly reduced the risk of radiographic progression or death by 61% versus placebo plus ADT in men with mHSPC (n=1,150; hazard ratio [HR]=0.39 [95% confidence interval (CI): 0.30-0.50]; P<0.0001).³

“Enzalutamide has been an established standard of care for men with advanced prostate cancer and has been prescribed to more than 610,000 patients worldwide since it was first approved in 2012,” said Andrew Krivoschik, M.D., Ph.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. “This new indication for enzalutamide provides men with mHSPC a much-needed, additional therapy option earlier in their treatment journey. We look forward to working with health authorities across Europe to ensure men with mHSPC have access to enzalutamide as soon as possible.”

The safety analyses of the ARCHES trial appear consistent with the safety profile of enzalutamide in previous clinical trials in CRPC. In ARCHES, Grade 3 or greater adverse events

(AEs) (defined as severe/disabling or life-threatening) were similar for patients receiving both enzalutamide plus ADT and those who received placebo plus ADT (24.3% vs. 25.6%).³

The EC marketing authorization for enzalutamide in men with mHSPC is applicable to European Union (EU) member countries, and is also valid in Iceland, Norway and Liechtenstein.⁴

Astellas has already reflected the impact from this approval in its financial forecast of the current fiscal year ending March 31, 2022.

About metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

In men with prostate cancer, the disease is considered metastatic once the cancer has spread outside of the prostate gland to other parts of the body.⁵ Men are considered hormone- (or castration-) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels.⁶ mHSPC has a median survival of approximately 3-4 years for men starting treatment with ADT.¹

About XTANDI™ (enzalutamide)

Enzalutamide is an androgen receptor signaling inhibitor indicated in the EU for the treatment of adult men with:²

1. Metastatic hormone-sensitive prostate cancer (mHSPC, also known as metastatic castration-sensitive prostate cancer or mCSPC) in combination with ADT.
2. High-risk non-metastatic castration-resistant prostate cancer (CRPC).
3. Metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. It is also indicated in adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

Important Safety Information

For important Safety Information for enzalutamide please see the full Summary of Product Characteristics at: https://www.ema.europa.eu/en/documents/product-information/xtandi-epar-product-information_en.pdf.

About ARCHES

The company-sponsored, Phase 3, randomized, double-blind, placebo-controlled, multinational ARCHES trial (NCT02677896) enrolled 1,150 patients with mHSPC at sites in the U.S., Canada, Europe, South America, and the Asia-Pacific region. Patients in the trial were randomized to receive enzalutamide 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 radiographic progression-free survival (rPFS) assessed by blinded independent central review. rPFS was defined as the time from randomization to radiographic disease progression at any time or death within 24 weeks after study drug discontinuation. Radiographic disease progression was defined by identification of two or more new bone lesions on a bone scan with confirmation (Prostate Cancer Working Group 2 criteria) and/or progression in soft tissue disease. Patients were stratified by volume of disease (low vs high) and prior docetaxel therapy for prostate cancer (no prior docetaxel, 1-5 cycles, or 6 prior cycles).

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 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.

Astellas 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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References

¹ Mottet N, et al. Updated Guidelines for Metastatic Hormone-sensitive Prostate Cancer: Abiraterone Acetate Combined with Castration Is Another Standard. Eur Urol. 2018;3:316-321.

² European Medicines Agency. Xtandi Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/xtandi-epar-product-information_en.pdf. Last accessed April 2021.

³ Armstrong A, et al. Phase 3 study of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo (PBO) in metastatic hormone-sensitive prostate cancer (mHSPC): the ARCHES trial. J Clin Oncol. 2019;7:687.

⁴ European Medicines Agency. Authorization of medicines. Available at: <https://www.ema.europa.eu/about-us/what-we-do/authorisation-medicines>. Last accessed April 2021.

⁵ Cancer.net. Prostate Cancer: Types of Treatment (03-2018). <https://www.cancer.net/cancer-types/prostate-cancer/types-treatment>. Last accessed April 2021.

⁶ American Society of Clinical Oncology. ASCO Answers: Prostate Cancer (2018). http://www.cancer.net/sites/cancer.net/files/asco_answers_guide_prostate.pdf. Last accessed April 2021.