Press Release

Astellas Receives European Approval for XTANDI™ (enzalutamide) for Adult Men with High-Risk Non-Metastatic Castration-Resistant Prostate Cancer

Results from the PROSPER trial show a median metastasis-free survival (MFS) of 36.6 months for enzalutamide plus androgen deprivation therapy (ADT) vs. 14.7 months for men who received placebo plus ADT[1]

TOKYO, October 29, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced today that the European Commission (EC) has approved a new indication for XTANDI (enzalutamide) for the treatment of adult men with high-risk, non-metastatic, castration-resistant prostate cancer (nmCRPC),[2] making it one of the first treatments approved for this critical stage of disease, currently associated with a significant unmet medical need. Enzalutamide was first approved by the EC in June 2013 and is already indicated in the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) in whom chemotherapy is not yet clinically indicated or whose disease has progressed on or after docetaxel therapy.[2]

The approval is based on the results from the pivotal phase 3 PROSPER trial which evaluated enzalutamide plus ADT vs. placebo plus ADT in patients with nmCRPC and rapidly rising prostate-specific antigen (PSA) levels, as defined by a PSA doubling time of 10 months or less and a PSA level of ≥ 2 ng/ml.[1]

"This new approval is important progress for men with CRPC, who now have enzalutamide as a treatment option regardless of whether or not they have detectable metastatic disease," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "We are committed to working with health authorities across Europe to ensure that enzalutamide is made available as soon as possible to men with high-risk nmCRPC."

The EC marketing authorisation for enzalutamide is applicable to the 28 European Union (EU) member countries plus Iceland, Norway and Liechtenstein.[3]

Astellas reflected the impact from this approval its financial forecasts of the current fiscal year ending March 31, 2019

About Enzalutamide
Enzalutamide is an oral, once-daily androgen receptor signaling inhibitor. Enzalutamide directly targets the androgen receptors (AR) and exerts its effects on three steps of the AR signaling pathway:[2]

- Inhibits androgen binding: Androgen binding induces a conformational change that triggers activation of the receptor[2]
- Prevents nuclear translocation: Translocation of the AR to the nucleus is an essential step in AR-mediated gene regulation[2]
- Impairs DNA binding: Binding of the AR to the DNA is essential for modulation of gene expression[2]

Enzalutamide is currently approved in Japan for castration-resistant prostate cancer[7] and in July 2018 the United States Food and Drug Administration (FDA) broadened the approved indication for enzalutamide to include men with nmCRPC.[8]

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.

Astellas Forward-Looking Statement
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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