

NEWS RELEASE



May 22, 2019

Launch of ERLEADA® (apalutamide) 60mg tablet for the treatment of prostate cancer

Nippon Shinyaku Co., LTD. (Nippon Shinyaku; Headquarters, Kyoto; President, Shigenobu Maekawa) announced that regarding ERLEADA® (apalutamide) 60mg tablet for the treatment of prostate cancer to be co-promoted with Nippon Shinyaku and Janssen Pharmaceutical K.K. (Janssen; Headquarters, Tokyo; President, Chris Hourigan), its NHI price listing was published as of today and Janssen will launch it on May 30, 2019.

Janssen obtained the marketing approval of ERLEADA® (apalutamide) 60mg tablet for the treatment for adults with castration-resistant prostate cancer without distant metastases in March this year.

ERLEADA® is orally available androgen receptor (AR) signal inhibitor that blocks androgen signaling pathway in prostate cancer cells. ERLEADA® inhibits the proliferation of cancer cells by three mode of actions, which include to prevent androgen from binding to AR, AR from blocking AR nuclear translocation, or AR from binding to DNA domain of cancer cells.

Nippon Shinyaku entered into the co-promotion agreement with Janssen in January this year. Under the terms of this agreement, providing appropriate medical information to healthcare professionals and patients and collection of the information on ERLEADA® will be undertaken by both companies.

Drug Information on ERLEADA® 60mg tablet

Product name	ERLEADA® 60mg tablet
Generic name	apalutamide
Indication	castration-resistant prostate cancer without distant metastases
Dosage and administration	Normally to adult, 240mg of apalutamide is orally administered one a day. Dosage should be reduced as needed depend on the patient's condition.
Date of approval	March 26, 2019
Date of NHI price listing	May 22, 2019
Date of launch	May 30, 2019
Drug price	ERLEADA® 60mg tablet (1 tablet/60mg) : 2,281.90 yen
Marketing authorization holder	Janssen Pharmaceutical K.K.
Co-promotor	Nippon Shinyaku Co., Ltd.

Co-promotion agreement

Under the term of the co-promotion agreement in Japanese territory concluded in January 2019, both companies will contribute to healthcare professionals and patients by providing appropriate medical information and collection of the information on ERLEADA®.

About Nippon Shinyaku

Our mission is to help people lead healthier and happier lives. Through creating unique medicines that will bring hope to patients and families struggling with illness, we aim to be an organization trusted by the community. Urology is the most focusing therapeutic area in Nippon Shinyaku. Please visit our website (<http://www.nippon-shinyaku.co.jp>) for products in urology etc.

Contact

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