NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

March 26, 2019

MHLW approval of ERLEADA® (apalutamide) 60mg tablet
For the treatment for castration-resistant prostate cancer without distant metastases

Nippon Shinyaku Co., LTD. (Nippon Shinyaku; Headquarters, Kyoto; President, Shigenobu Maekawa) announced as of today regarding ERLEADA® (apalutamide) 60mg tablet to be co-promoted with Nippon Shinyaku and Janssen Pharmaceutical K.K. (Janssen; Headquarters, Tokyo; President, Chris Hourigan) that Janssen obtained the Ministry of Health, Labour and Welfare (MHLW) approval of ERLEADA® (apalutamide) 60mg tablet for the treatment for adults with castration-resistant prostate cancer without distant metastases.

ERLEADA® is a novel and 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. ERLEADA® has been approved as the treatment of patients with castration-resistant prostate cancer without distant metastases in February, 2018 in the U.S. and in January, 2019 in the European Union respectively.

Nippon Shinyaku entered into the co-promotion agreement in Japan with Janssen which holds the marketing authorization for ERLEADA®. Under the terms of this agreement, promotion of ERLEADA® to healthcare professionals and patients will be undertaken by both companies.

About the pivotal SPARTAN trial [1,2]

The pivotal SPARTAN clinical trial assessed the safety and efficacy of ERLEADA® versus placebo receiving Androgen Deprivation Therapy (ADT) in patients with castration-resistant prostate cancer without distant metastases. The study was allocated in a 2:1 ratio in a random manner. Data from the trial showed ERLEADA® in combination with ADT decreased the risk of metastasis or death by 70 percent compared to placebo in combination with ADT (HR = 0.297; 95% CI, 0.244-0.362; $p<0.0001$). The median MFS was 40.51 months for ERLEADA® in combination with ADT compared to 15.70 months for placebo in combination with ADT.

[1] Smith MR, et al.: N Engl J Med., 378, 1408-1418, 2018

[2] Clinical result of apalutamide for patients with high-risk castration-resistant prostate cancer without metastases (ARN-509-003study)

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.

Media Contact

Corporate Communications Dept., Nippon Shinyaku

TEL: +81-75-321-9103 FAX: +81-75-321-9128