NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

MHLW approval of ERLEADA® (apalutamide) for the Treatment of Patients with Prostate Cancer with Distant Metastases

Kyoto, Japan, May 29, 2020 – Nippon Shinyaku Co., LTD. (Nippon Shinyaku; HQs, Kyoto; President, Shigenobu Maekawa) announced today that Janssen Pharmaceutical K.K. (Janssen; HQs, Tokyo; President, Chris Hourigan) which is the marketing authorization holder of ERLEADA® 60mg tablet (apalutamide tablet) has obtained an expanded approval for the treatment of men with prostate cancer with distant metastases from the Ministry of Health, Labor and Welfare (MHLW).

TITAN (PCR3002 study) is a global phase 3, randomized, placebo-controlled, double-blind study in prostate cancer patients with bone metastasis within 6 months after androgen deprivation therapy (ADT). Safety, tolerability and effectiveness of ERLEADA® were tested in the study. Overall survival (OS) and radiographic progression-free survival (rPFS) were evaluated as dual primary endpoints. Results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in *The New England Journal of Medicine*. Please refer to Janssen Website (www.janssen.com/japan/) in detailed information.

Prostate cancer is one of the most common cancers in men and approximately 78,500 men were diagnosed in 2019 in Japan. It is estimated that 10-20 percent of the patients are newly diagnosed with locally advanced prostate cancer, and 5-10 percent of patients are with prostate cancer with distant metastases to bones or visceral organs.

Nippon Shinyaku concluded a co-promotion agreement of ERLEADA® in January, 2019 and ZYTIGA® in February, 2020 with Janssen. Nippon Shinyaku will contribute the treatment of prostate cancer in Japan by providing to and collecting from medical facilities the medical information appropriately through further collaboration with Janssen.

About ERLEADA®

ERLEADA® is a selective next generation oral androgen receptor inhibitor that inhibits the action of testosterone in prostate cancer cells and works by preventing androgen from binding to the androgen receptor (AR) It selectively binds to the ligand-binding domain of AR and blocks AR nuclear translocation or binding to androgen response elements. It antagonizes AR-mediated signaling in AR overexpressing human CRPC cell lines.

About the TITAN Study[1,2]

The study included 1,052 patients with prostate cancer with bone metastasis within 6 months after ADT. Patients were randomized and received either ERLEADA® plus ADT, or placebo plus ADT. Dual primary endpoints of the study were OS and rPFS and secondary endpoints included time to cytotoxic chemotherapy, time to pain progression, time to chronic opioid use, and time to skeletal-related event.

Please visit ClinicalTrials.gov for additional information.

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