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ASIA EDITION

Darolutamide gets marketing authorization in Japan

January 24, 2020 | News

The approval is based on the Phase III ARAMIS trial evaluating the efficacy and safety of darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT, showing a highly significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS)



The Japanese Ministry of Health, Labor and Welfare (MHLW) has granted marketing authorization for darolutamide, under the brand name Nubeqa®, for the treatment of men with non-metastatic castration-resistant prostate cancer (nmCRPC).

The approval is based on the Phase III ARAMIS trial evaluating the efficacy and safety of darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT, showing a highly significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS).

The androgen receptor inhibitor (ARi), which is jointly developed by Orion and Bayer is already approved in the U.S. and Brazil and filings in the European Union and other regions are underway or planned by Bayer.

“Patients with nmCRPC are usually asymptomatic, but have a rising blood prostate specific antigen (PSA) despite ADT treatment, and it is important to prevent their cancer from becoming metastatic and symptomatic. The overarching goals of treatment in this setting are to delay the spread of prostate cancer and limit the burdensome side effects of therapy. Darolutamide provides nmCRPC patients now also in Japan a new therapeutic option that addresses these questions” said Christer Nordstedt, Senior Vice President, Research and Development, Orion Corporation.

In the ARAMIS trial, overall survival (OS) and time to pain progression were additional secondary efficacy endpoints. At the time of final MFS analysis, a positive trend in OS was observed; OS data were not yet mature. The MFS result was additionally supported by a delay in time to pain progression as compared to placebo plus ADT. All other secondary endpoints, time to cytotoxic chemotherapy, and time to a symptomatic skeletal event (SSE), demonstrated a benefit in favor of darolutamide.