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USFDA approves Bayer's darolutamide for Prostate Cancer

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The compound, which is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company, was approved under the FDA Priority Review designation

The U.S. Food and Drug Administration (FDA) has approved darolutamide, a non-steroidal androgen receptor inhibitor (ARi), under the brand name Nubeqa®.

The FDA approval is for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) and is based on the Phase III ARAMIS trial evaluating darolutamide plus androgen deprivation therapy (ADT), which demonstrated a highly significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS), with a median of 40.4 months versus 18.4 months for placebo plus ADT ($p<0.0001$).

MFS is defined as the time from randomization to the time of first evidence of blinded independent central review (BICR)-confirmed distant metastasis or death from any cause within 33 weeks after the last evaluable scan, whichever occurred first. The compound, which is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company, was approved under the FDA Priority Review designation, which is reserved for medicines that may provide significant improvements in the safety or effectiveness of the treatment for serious conditions. The androgen receptor inhibitor has a distinct chemical structure that binds to the receptor with high affinity and exhibits strong antagonistic activity, thereby inhibiting the receptor function and the growth of prostate cancer cells.

Matthew Smith, Director of the Genitourinary Malignancies Program, Massachusetts General Hospital Cancer Center said, "Patients at this stage of prostate cancer typically don't have symptoms of the disease. The overarching goals of treatment in this setting are to delay the spread of prostate cancer and limit the burdensome side effects of therapy. This approval marks an important new option for the prostate cancer community."

Prostate cancer that is treated with ADT but keeps progressing even when the amount of testosterone is reduced to very low levels in the body is known as castration-resistant prostate cancer (CRPC). In the U.S., over 73,000 men are estimated to have a CRPC diagnosis in 2019. About one-third of men with non-metastatic CRPC go on to develop metastases within two

years.

Robert LaCaze, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of the Oncology Strategic Business Unit said, “With the approval of darolutamide, we now have a new therapy that extends MFS and allows physicians greater flexibility to treat men living with nmCRPC. Bayer is proud to take this latest step forward in the nmCRPC treatment landscape. Darolutamide is the newest addition to our prostate cancer portfolio and reflects Bayer's commitment to finding treatments for men at different stages along the prostate cancer continuum.”

In the ARAMIS trial, overall survival (OS) and time to pain progression were additional secondary efficacy endpoints. A positive trend in OS was observed; OS data were not yet mature at the time of final MFS analysis. 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, demonstrated a benefit in favor of darolutamide.

Bayer has filed for approval of the compound in the European Union (EU), Japan and with other health authorities.