BioSpectrum the business of Bio & Health Sciences

Bayer completes NDA submission to USFDA for cancer drug darolutamide

27 February 2019 | News

Bayer has been granted Fast Track designation by the FDA for darolutamide in men with nmCRPC

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. The company has announced the completion of the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational drug darolutamide.

The submission, which was initiated in December 2018, is based on data from the Phase III ARAMIS trial in men with non-metastatic castration-resistant prostate cancer (nmCRPC).These data were recently presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in San Francisco.

Bayer has been granted Fast Track designation by the FDA for darolutamide in men with nmCRPC. Bayer is also in discussions with other health authorities regarding a submission of darolutamide. The compound is being developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.