FDA Approves Erleada for Non-Metastatic Castration-Resistant Prostate Cancer

Erleada prolonged the time to disease progression or death in the SPARTAN trial.

February 14, 2018 By Food and Drug Administration (FDA)

On February 14, 2018, the Food and Drug Administration approved apalutamide (Erleada, Janssen Biotech, Inc.) for patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).

Approval was based on a multicenter, double-blind, clinical trial (SPARTAN, NCT01946204) randomizing 1,207 patients with NM-CRPC (2:1) to receive either apalutamide, 240 mg orally once daily in combination with ADT (medical castration or surgical castration) (n=806), or placebo once daily with ADT (n=401).

The major efficacy endpoint was metastasis-free survival (MFS). MFS was defined as the time from randomization to the time of first evidence of distant metastasis (new bone or soft tissue lesions or enlarged lymph nodes outside the pelvis), or death due to any cause, whichever occurred first. The estimated median MFS was 40.5 months for patients receiving apalutamide and 16.2 months for those receiving placebo (hazard ratio 0.28; 95% CI: 0.23, 0.35; p<0.0001).

The most common adverse reactions in at least 10% of patients were fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema.

The recommended apalutamide dose is 240 mg (four 60 mg tablets) administered orally once daily.

Full prescribing information is available at: ERLEADA™.

FDA granted this application priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at www.fda.gov/medwatch/report, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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This announcement originally appeared on the FDA's website.
