FDA OKs Janssen’s apalutamide product

Feb. 21, 2018—Janssen Pharmaceuticals announced the FDA approval of Erleada (apalutamide) for the treatment of patients with nonmetastic castration-resistant prostate cancer. Erleada is an androgen receptor inhibitor that binds directly to the ligand-binding domain of the androgen receptor. It inhibits AR nuclear translocation and DNA binding and impedes AR-mediated transcription.

This application was granted FDA priority review based on data from the phase three SPARTAN study, which demonstrated a 72 percent reduction in risk of distant metastasis or death and an increase in median metastasis-free survival by more than two years (difference of 24.31 months) in patients with NM-CRPC. Patients in the trial received either Erleada or a placebo. All patients were also treated with hormone therapy, either with gonadotropin-releasing hormone analog therapy or with surgery to lower the amount of testosterone in their body.

“The need to delay metastasis is critical to the treatment of prostate cancer. Nearly 90 percent of patients with castration-resistant prostate cancer will eventually develop bone metastases, at which point the prognosis sharply worsens,” Mathai Mammen, MD, PhD, global head of Janssen research and development, said in a statement. “We are excited about what this approval means for patients living with prostate cancer, and that physicians now have an important and much-needed treatment option that has been shown to delay the progression of castration-resistant prostate cancer.”

Erleada is the first FDA-approved treatment for patients with nonmetastic castration-resistant prostate cancer.

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