Grupo Português Génito - Urinário

GPGU – NOTÍCIAS

FDA Approves Abiraterone Acetate in Combination With Prednisone for High-Risk Metastatic Castration-Sensitive Prostate Cancer

On February 7, 2018, the U.S. Food and Drug Administration (FDA) approved abiraterone acetate (Zytiga) tablets in combination with prednisone for metastatic high-risk castration-sensitive prostate cancer.

The FDA initially approved abiraterone acetate with prednisone in 2011 for patients with metastatic castration-resistant prostate cancer who had received prior chemotherapy, and expanded the indication in 2012 for patients with metastatic castration-resistant prostate cancer.

LATITUDE Trial

The current approval was based on LATITUDE, a placebo-controlled international clinical trial that randomized 1,199 patients with metastatic high-risk castration-sensitive prostate cancer. Patients received either abiraterone acetate 1,000 mg orally once daily with prednisone 5 mg once daily (n = 597), or placebos orally once daily (n = 602). Patients in both arms received a gonadotropin-releasing hormone or had a bilateral orchiectomy. The major efficacy endpoint was overall survival. Median overall survival was not estimable and 34.7 months in the abiraterone acetate and placebos arms, respectively (hazard ratio [HR] = 0.621; 95% confidence interval [CI] = 0.509–0.756; P < .0001). The median time-to-initiation of chemotherapy was not reached for patients on abiraterone

acetate with prednisone and 38.9 months for those receiving placebos (HR = 0.44; 95% CI = 0.35–0.56; P < .0001).

The most common adverse reactions in at least 5% of patients receiving abiraterone acetate on LATITUDE were hypertension, hot flush, hypokalemia, increased alanine aminotransferase or aspartate aminotransferase, headache, urinary tract infection, upper respiratory tract infection, and cough.

The recommended dose for abiraterone acetate for metastatic castration-sensitive prostate cancer is 1,000 mg orally once daily with prednisone 5 mg orally once daily. Patients receiving abiraterone acetate should also receive a gonadotropin-releasing hormone analog concurrently or should have had bilateral orchiectomy.