FDA Approves Zytiga for High-Risk Metastatic Prostate Cancer

Approval was based on LATITUDE trial of patients with metastatic high-risk castration-sensitive prostate cancer.

February 7, 2018 By Food and Drug Administration (FDA)

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

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

Today's approval was based on LATITUDE (NCT01715285), a placebo controlled international clinical trial that randomized 1,199 patients with metastatic high-risk CSPC. 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 (OS). Median OS was not estimable and 34.7 months in the abiraterone acetate and placebos arms, respectively (HR 0.621; 95% CI: 0.509, 0.756; p<0.0001). 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<0.0001).

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 Zytiga for metastatic CSPC is 1,000 mg orally once daily with prednisone 5 mg orally once daily. Patients receiving ZYTIGA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202379s024lbl.pdf.

FDA granted priority review for this application and it was approved more than a month ahead of

the due date. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

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 http://www.fda.gov/medwatch/report.htm, 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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