Akeega™ (niraparib/abiraterone) – New drug approval

- On August 11, 2023, Janssen announced the FDA approval of Akeega (niraparib/abiraterone), for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).
    - Patients should be selected for therapy based on an FDA-approved test for Akeega.
- Akeega is the first dual action combination tablet approved for BRCAm mCRPC. Niraparib is currently available under the brand name (Zejula) and abiraterone is available generically.
    - Zejula is approved for first-line maintenance treatment of advanced ovarian cancer and maintenance treatment of recurrent germline BRCAm ovarian cancer.
    - Abiraterone is approved for the treatment of patients with mCRPC and metastatic high-risk castration-sensitive prostate cancer.
- The efficacy of Akeega was established in Cohort 1 of MAGNITUDE, a randomized, double-blind, placebo-controlled study in 423 patients with homologous recombination repair (HRR) gene-mutated (HRRm) mCRPC. Patients were randomized to receive Akeega or placebo plus abiraterone until unacceptable toxicity or progression. Of the patients enrolled, 225 had BRCAm. The major outcome measure was radiographic progression free survival (rPFS). Overall survival (OS) was an additional outcome measure.
    - A statistically significant improvement in rPFS for Akeega compared to placebo plus abiraterone was observed in BRCAm patients, and the Cohort 1 intention to treat (ITT) population. In an exploratory analysis in the subgroup of 198 (47%) patients with non-BRCA mutations, the rPFS hazard ratio (HR) was 0.99 (95% CI: 0.67, 1.44) and the OS HR was 1.13 (95% CI: 0.77, 1.64), indicating that the improvement in the ITT population was primarily attributed to the results seen in the subgroup of patients with BRCAm.
    - In the BRCAm subgroup, median rPFS was 16.6 months with Akeega vs. 10.9 months with placebo plus abiraterone (HR 0.53, 95% CI: 0.36, 0.79; p = 0.0014).
    - In an exploratory OS analysis in the subgroup of patients with BRCAm, the median in the Akeega arm was 30.4 months and 28.6 months in the placebo plus abiraterone arm, with an OS HR of 0.79 (95% CI: 0.55, 1.12).
- Warnings and precautions for Akeega include myelodysplastic syndrome/acute myeloid leukemia; myelosuppression; hypokalemia, fluid retention, and cardiovascular adverse reactions; hepatotoxicity; adrenal insufficiency; hypoglycemia; increased fractures and mortality in combination with radium 223 dichloride; posterior reversible encephalopathy syndrome; and embryo-fetal toxicity.
- The most common adverse reactions (≥ 10%), including laboratory abnormalities, with Akeega use were decreased hemoglobin, decreased lymphocytes, decreased white blood cells, musculoskeletal pain, fatigue, decreased platelets, increased alkaline phosphatase, constipation, hypertension, nausea, decreased neutrophils, increased creatinine, increased potassium, decreased potassium, increased AST, increased ALT, edema, dyspnea, decreased appetite, vomiting, dizziness, COVID-19, headache, abdominal pain, hemorrhage, urinary tract infection, cough, insomnia, increased bilirubin, weight decreased, arrhythmia, fall, and pyrexia.
- The recommended dosage of Akeega is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone daily until disease progression or unacceptable toxicity.

Continued . . .

    - Patients receiving Akeega should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

- Janssen's launch plans for Akeega are pending. Akeega will be available as tablets containing 50 mg niraparib/500 mg abiraterone acetate or 100 mg niraparib/500 mg abiraterone acetate.

Optum

At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.

© 2023 Optum, Inc. All rights reserved. ORX6547968A-TEMPLATE_220208