FDA approves lynparza for BRCA-mutated metastatic castration-resistant prostate cancer

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The U.S. Food and Drug Administration approved Lynparza (olaparib) with abiraterone and prednisone (or prednisolone) for adult patients with deleterious or suspected deleterious *BRCA*-mutated, metastatic, castration-resistant prostate cancer (mCRPC).

The approval was based on findings from the PROpel trial in which 796 patients with mCRPC were randomly assigned (1:1) to receive either Lynparza with abiraterone or placebo with abiraterone and also received prednisone or prednisolone. According to the results of the study, there was a statistically significant improvement in investigator-assessed radiological progression-free survival for Lynparza with abiraterone versus placebo with abiraterone.

A subgroup analysis suggested that improvement in radiological progression-free survival was driven by patients with *BRCA*-mutated cancer. Lynparza was approved with a companion diagnostic test to assess *BRCA* mutational status.

For patients taking Lynparza, the most common adverse reactions included anemia (48 percent), fatigue (38 percent), nausea (30 percent), diarrhea (19 percent), decreased appetite (16 percent), lymphopenia (14 percent), dizziness (14 percent), and abdominal pain (13 percent). Nearly one in five patients (18 percent) required at least one blood transfusion.

Approval of Lynparza was granted to AstraZeneca.

More information: More Information

lynparza-brca-mutated-metastatic-castration-resistant.html