New Drug Approvals

Generic Name (Trade Nameâ€"Company)

Uses/Notes

October 29, 2018

Talazoparib

(Talzenna—Pfizer)

FDA approves talazoparib for gBRCAm HER2-negative locally advanced or metastatic breast cancer

FDA approved talazoparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), human epidermal growth factor receptor 2–negative locally advanced or metastatic breast cancer. Patients must be selected for therapy on the basis of an FDA-approved companion diagnostic, the BRACAnalysis CDx test (Myriad Genetic Laboratories).

Approval was based on an open?label trial randomizing 431 patients (2:1) with gBRCAm HER2?negative locally advanced or metastatic breast cancer to receive talazoparib (1 mg) or physician's choice of chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine). All patients were required to have a known deleterious or suspected deleterious gBRCA mutation and must have received no more than three prior cytotoxic chemotherapy regimens for locally advanced or metastatic disease. Patients were required to have received treatment with an anthracycline and/or a taxane (unless contraindicated) in the neoadjuvant, adjuvant, and/or metastatic treatment setting.

The prescribing information includes warnings and precautions for myelodysplastic syndrome/acute myeloid leukemia, myelosuppression, and embryo–fetal toxicity. Most common (?20%) adverse reactions of any grade were fatigue, anemia, nausea, neutropenia, headache, thrombocytopenia, vomiting, alopecia, diarrhea, and decreased appetite.

The recommended talazoparib dose is 1 mg taken as a single-oral daily dose, with or without food.

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