Talzenna® (talazoparib) – New drug approval

- On October 16, 2018, Pfizer announced the FDA approval of Talzenna (talazoparib) for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.
    - Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.
- Talzenna is an inhibitor of certain poly (ADP-ribose) polymerase (PARP) enzymes, which play a role in DNA repair. *In vitro* studies have shown that Talzenna-induced cytotoxicity results in DNA damage, decreased cell proliferation, and apoptosis.
- The safety and efficacy of Talzenna are based on data from an open-label clinical study of 431 patients with gBRCAm HER2- negative locally advanced or metastatic breast cancer. Patients received Talzenna or provider's choice of chemotherapy. The major efficacy outcome measure was progression-free survival (PFS).
    - A statistically significant improvement in PFS was demonstrated for Talzenna (8.6 months) vs. chemotherapy (5.6 months) (HR = 0.54, 95% CI: 0.41, 0.71; $p < 0.0001$).
    - The overall survival data were not mature at the time of the final PFS analysis (38% of patients had died).
- Warnings and precautions of Talzenna include myelodysplastic syndrome/acute myeloid leukemia, myelosuppression, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) reported with Talzenna use were fatigue, anemia, nausea, neutropenia, headache, thrombocytopenia, vomiting, alopecia, diarrhea, decreased appetite.
- The most common laboratory abnormalities (≥ 25%) with Talzenna use were decreases in hemoglobin, platelets, neutrophils, lymphocytes, leukocytes, and calcium; and increases in glucose, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase.
- The recommended dose of Talzenna is 1 mg taken as a single daily dose, with or without food.
    - Patients should be treated until disease progression or unacceptable toxicity occurs.
- Pfizer plans to launch Talzenna on October 29, 2018. Talzenna will be available as 0.25 mg and 1 mg capsules.