FDA Approves Lynparza Maintenance Therapy for Pancreatic Cancer

PARP inhibitor delays disease progression when used after successful chemotherapy.

December 31, 2019 By Liz Highleyman

On December 30, the Food and Drug Administration (FDA) approved Lynparza (olaparib) as maintenance therapy for people with metastatic pancreatic cancer carrying harmful BRCA mutations who have not progressed on platinum-based chemotherapy.

“Metastatic pancreatic cancer patients have been waiting a long time for new therapy options for their devastating disease,” Julie Fleshman of the Pancreatic Cancer Action Network said in an AstraZeneca press release. "Today’s approval of Lynparza provides an exciting new treatment option for patients with germline BRCA-mutated metastatic pancreatic cancer."

Pancreatic cancer is often diagnosed at a late stage and is difficult to treat. Relapse after chemotherapy is common, and survival is typically short. Around 5% of people with pancreatic cancer have harmful germline (inherited) BRCA mutations, best known for raising the risk of breast and ovarian cancer. Pancreatic cancer patients with these mutations often respond to platinum-based chemotherapy drugs, such as cisplatin, but these medications have cumulative toxicities and better-tolerated therapies are needed for long-term maintenance.

Lynparza, from AstraZeneca and Merck, is a targeted therapy that inhibits poly ADP-ribose polymerase, or PARP proteins, which play a role in DNA repair. Blocking PARP leads to more DNA breaks in cancer cells, which can halt tumor growth. People with certain BRCA mutations can’t fix this kind of DNA damage, so BRCA-related cancers are particularly susceptible to these drugs.

The new approval is for maintenance therapy—intended to maintain stable disease without further progression—in people with metastatic pancreatic adenocarcinoma with known or suspected harmful BRCA1 or BRCA2 mutations whose disease has not progressed after at least 16 weeks on a first-line platinum chemotherapy regimen. Lynparza was previously approved for the treatment of advanced ovarian cancer and HER2-negative breast cancer in people with harmful BRCA mutations, and for ovarian cancer maintenance therapy. A companion diagnostic test is available to help determine which patients are eligible to use Lynparza.

This approval was supported by results from the Phase III POLO trial, which included 154 participants with metastatic pancreatic cancer who had received first-line platinum-based

chemotherapy for at least 16 weeks without disease progression. Just over half were men, and the median age was 57. They were randomly assigned to receive twice-daily Lynparza or placebo tablets until they experienced disease progression or unacceptable side effects.

As described at this year's American Society of Clinical Oncology annual meeting and in The New England Journal of Medicine, objective response rates, meaning complete or partial tumor regression, were 23% in the Lynparza group versus 12% in the placebo group. The median duration of response was substantially longer with Lynparza compared with the placebo (24.9 months versus 3.7 months, respectively).

Participants who took Lynparza went about twice as long as placebo recipients before they experienced disease progression. The median progression-free survival duration was 7.4 months versus 3.8 months, respectively—a 47% reduction in the risk of disease progression or death. After a year on treatment, 34% of Lynparza recipients and 15% of placebo recipients were still alive without worsening of their disease; after two years, the corresponding rates were 22% and 10%.

Although overall survival data are not yet mature, interim results show that the median duration was statistically similar in the Lynparza and placebo groups (18.9 months versus 18.1 months). A larger survival benefit could become apparent with longer follow-up. Earlier this month, an FDA advisory committee voted 7 to 5 in favor of approving Lynparza for this indication, with the dissenters arguing that further overall survival data are needed and questioning whether the drug offers real clinical benefit.

Treatment with Lynparza is generally safe. The most common adverse events include fatigue, nausea, vomiting, diarrhea, abdominal pain, dizziness, muscle and joint pain, headache, taste changes (dysgeusia), decreased appetite, dry mouth and constipation. Lynparza can cause depletion of red blood cells (anemia), white blood cells (neutropenia) and platelets (thrombocytopenia), which can lead to fatigue, infections and easy bleeding. Potentially serious side effects may include lung inflammation and increased risk of leukemia or myelodysplastic syndrome. However, just 6% of participants in the POLO study stopped treatment due to side effects. There were no significant differences in health-related quality of life between the Lynparza and placebo groups.

"Today's approval of olaparib based on the POLO results gives clinicians an important first-line maintenance treatment option which nearly doubled the progression-free survival benefit in patients with germline BRCA-mutated metastatic pancreatic cancer," said trial investigator Hedy Kindler, MD, of University of Chicago Medicine.

Click here for full prescribing information for Lynparza.
Click here to read the POLO study abstract.
Click here to learn more about pancreatic cancer.

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