FDA Approves New Treatment Option for Ovarian Cancer

Elahere, a new antibody-drug conjugate, shrank tumors in about a third of treatment-experienced patients.

November 17, 2022 By Liz Highleyman

On November 14, the Food and Drug Administration (FDA) granted accelerated approval of Elahere (mirvetuximab soravtansine), a novel antibody-drug conjugate for people with previously treated ovarian, fallopian tube or primary peritoneal cancer who no longer respond to platinum chemotherapy. It is the first new treatment for advanced ovarian cancer in nearly a decade.

Ovarian cancer is often detected at an advanced stage, and it is difficult to treat. About 20,000 women will be diagnosed with ovarian cancer and nearly 13,000 are expected to die from it this year, according to the American Cancer Society. Primary peritoneal cancer starts in the tissue that lines the abdominal wall and covers the abdominal organs. Standard therapy usually involves surgery followed by platinum-based chemotherapy.

Elahere, from ImmunoGen, is an antibody-drug conjugate that uses a monoclonal antibody targeting folate receptor alpha (FRα) to deliver a potent chemotherapy drug. It is approved for adults with FRα-positive epithelial ovarian, fallopian tube or primary peritoneal cancer who have received one to three prior systemic treatment regimens and have developed resistance to platinum chemotherapy. Patients are selected for therapy using an FDA-approved companion diagnostic test. Approximately 40% of ovarian cancer patients have high tumor FRα expression.

The accelerated approval was based on results from the Phase III SORAYA study, a single-arm clinical trial (NCT04296890) that included 106 patients with these types of cancer. They could have used up to three prior lines of systemic therapy; nearly half had tried a PARP inhibitor. All had to have taken Avastin (bevacizumab), a drug that interferes with blood vessel formation, but the FDA did not make this a requirement for use. All participants received Elahere, dosed according to body weight, administered via IV infusion every three weeks until patients experienced disease progression or unacceptable side effects.

As previously reported, the confirmed response rate, or tumor shrinkage as assessed by the trial investigators, was 32% for the 104 evaluable patients who received at least one dose of Elahere, including five people who achieved a complete response. The median duration of response was 6.9 months.

Treatment was generally safe, but many patients experienced side effects. The most common adverse reactions include vision impairment, dry eyes, cornea damage (keratopathy), fatigue, nausea, abdominal pain, diarrhea, constipation, peripheral neuropathy, decreased hemoglobin and white blood cell counts and elevated liver enzymes. The Elahere label includes a warning about severe eye problems, lung inflammation and peripheral nerve damage.

“The approval of Elahere is significant for patients with FRα-positive platinum-resistant ovarian cancer, which is characterized by limited treatment options and poor outcomes,” study investigator Ursula Matulonis, MD, of Dana-Farber Cancer Institute and Harvard Medical School, said in an Immunogen press release. “Elahere’s impressive anti-tumor activity, durability of response and overall tolerability observed in SORAYA demonstrate the benefit of this new therapeutic option.”

Drugs that receive accelerated approval based on overall response rate are expected to undergo further testing to confirm whether they provide clinical benefits such as delayed disease progression and improved survival; the FDA can rescind the approval if they fail to measure up. A randomized confirmatory trial dubbed MIRASOL is fully enrolled and results are expected in early 2023.

Click here for full prescribing information for Elahere.

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