FDA Approves Trodelvy for Triple-Negative Breast Cancer

The antibody-drug conjugate is the second drug approved for metastatic breast cancer in the course of a week.

April 13, 2021 By Liz Highleyman

Update: On April 13, 2021, the FDA granted regular full approval to Trodelvy for triple-negative breast cancer.

On April 22, 2020, the Food and Drug Administration (FDA) granted accelerated approval to Trodelvy (sacituzumab govitecan) for the treatment people with previously treated triple-negative breast cancer that has spread elsewhere in the body. This antibody-drug conjugate precisely delivers potent chemotherapy to tumors.

“Metastatic triple-negative breast cancer is an aggressive form of breast cancer with limited treatment options,” Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence, said in a press release. “There is intense interest in finding new medications to help treat metastatic triple-negative breast cancer. Today’s approval provides patients who’ve already tried two prior therapies with a new option.”

Breast cancer is classified according to the types of receptors it expresses. A majority of breast tumors carry estrogen or progesterone hormone receptors (known as HR-positive). Others express another receptor called HER2 and can be treated with HER2 inhibitors, such as Herceptin (trastuzumab). Triple-negative breast cancer doesn’t express any of these receptors and is harder to treat.

Trodelvy, from Immunomedics, uses a monoclonal antibody that targets Trop-2, a protein found in more than 90% of triple-negative breast tumors. The antibody delivers an active form of the chemotherapy drug irinotecan. Trodelvy is also being studied as a treatment for eight other hard-to-treat malignancies, including metastatic bladder cancer.

The accelerated approval was based on promising findings from a Phase II clinical trial that included 108 patients with metastatic triple-negative breast cancer who had received at least two prior treatments for metastatic disease. The median age was 55 years. Most had cancer that had spread to their internal organs. About 40% were on their third line of treatment, while about 60% had received four or more prior chemotherapy drugs.

All the study participants were treated with Trodelvy administered by IV infusion on days 1 and 8 in 28-day cycles.

The overall response rate, meaning complete or partial tumor shrinkage, was 33%, with a median duration of response of 7.7 months. More than half of responders remained in remission for at least six months, and 17% did so for at least a year.

The median progression-free survival duration, meaning participants were still alive without worsening of their disease, was 5.5 months. The median overall survival time was 13.0 months, with estimated survival rates of 79% at six months and 51% at 12 months.

“In our trial, Trodelvy demonstrated clinically meaningful responses in patients with difficult-to-treat metastatic [triple-negative breast cancer] and moves the needle toward better outcomes for patients with metastatic breast cancer,” study investigator Aditya Bardia, MD, MPH, of Massachusetts General Hospital Cancer Center and Harvard Medical School, said in an Immunomedics press release.

Treatment was generally safe, although side effects were common. Just over a third experienced serious adverse events, but only two people stopped treatment because of drug-related side effects.

The most common adverse reactions in people treated with Trodelvy include nausea, neutropenia (low white blood cell count), diarrhea, fatigue, anemia, vomiting, abdominal pain, decreased appetite, constipation, hair loss and rash. The drug’s prescribing information includes warnings about severe neutropenia and resulting infections, severe diarrhea, severe nausea and hypersensitivity reactions. The drug can cause fetal harm if used during pregnancy.

Drugs that receive accelerated approval based on response rates in early studies are expected to undergo further testing in larger randomized clinical trials to confirm clinical benefits, such as improved survival. Immunomedics recently announced that a Phase III trial of Trodelvy, known as ASCENT, was stopped ahead of schedule due to “compelling evidence of efficacy.” The company said results from that study are expected to be released later this year.

“The remarkable results we observed across multiple endpoints in the ASCENT study warranted early discontinuation of the trial and are indicative of a potential major advance in the treatment of this devastating disease that affects younger women and African-American women at higher rates,” Data Safety Monitoring Committee chair Julie Gralow, MD, of the University of Washington School of Medicine and the Fred Hutchinson Cancer Research Center, said in an Immunomedics press release.

Click here for full prescribing information for Trodelvy.

Click here to learn more about breast cancer.

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