FDA Approves Trodelvy for Most Common Type of Metastatic Breast Cancer

The antibody-drug conjugate is now approved for patients with hormone receptor-positive/HER2-negative or triple-negative breast cancer.

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On February 3, the Food and Drug Administration (FDA) approved Trodelvy (sacituzumab govitecan) for previously treated people with the most common type of locally advanced or metastatic breast cancer. It is now approved for patients with either hormone receptor-positive/HER2-negative or triple-negative breast cancer after trying other therapies.

Trodelvy is an antibody-drug conjugate that uses a monoclonal antibody targeting Trop-2, a common protein on breast tumors, to deliver a potent chemotherapy drug.

“This approval is significant for the breast cancer community, Hope Rugo, MD, of the UCSF Helen Diller Family Comprehensive Cancer Center, said in a Gilead Sciences press release. “We have had limited options to offer patients after endocrine-based therapy and chemotherapy, and to see a clinically meaningful survival benefit of more than three months with a quality of life benefit for these women is exceptional.”

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) and can be treated with hormone, or endocrine, therapy. Others express another receptor called HER2 and can be treated with HER2 inhibitors such as Herceptin (trastuzumab). HR-positive/HER2-negative breast cancer is the most common type, accounting for more than 80% of new cases. Trodelvy was previously approved for triple-negative breast cancer, which does not express any of these receptors and is harder to treat.

“Despite decades of advances, people living with pretreated HR-positive/HER2-negative metastatic breast cancer need new treatment options,” Rugo said. “Nearly all people with this type of breast cancer will eventually develop resistance to endocrine-based therapies and progress on available chemotherapies.”

The new approval was based on findings from the Phase III TROPiCS-02 trial, which enrolled 543

patients with inoperable locally advanced or metastatic HR-positive/ HER2-negative breast cancer who experienced progression after receiving other systemic therapies. They were randomly assigned to receive IV infusions of Trodelvy on days 1 and 8 of a 21-day cycle or a single chemotherapy drug (eribulin, vinorelbine, gemcitabine or capecitabine. They were treated until they experienced further disease progression or unacceptable side effects.

At the 2022 American Society of Clinical Oncology annual meeting, Rugo reported that Trodelvy improved progression-free survival. The median progression-free survival time was 5.5 months in the Trodelvy group versus 4.0 months in the chemotherapy group—a 34% reduction in the risk of disease progression or death.

At last year's European Society for Medical Oncology Congress, she reported that overall survival also improved. The median overall survival times were 14.4 months and 11.2 months, respectively—a 21% reduction in the risk of death. The overall response rate was also significantly higher for Trodelvy versus chemotherapy (21% versus 14%).

Treatment was generally safe, although side effects were common. Patients assigned to Trodelvy had more severe adverse events, but rates of treatment discontinuation due to side effects was similar in both groups. What's more, people who received Trodelvy reported less fatigue and delayed deterioration of quality of life.

According to the Trodelvy package insert, the most common adverse reactions are decreased white blood cell counts, decreased hemoglobin (anemia), diarrhea, nausea, vomiting, constipation, decreased appetite, fatigue, hair loss and various laboratory abnormalities.

"The FDA approval is an important step forward for both women and men living with metastatic breast cancer, especially for those individuals whose tumor is no longer responding to endocrine-based therapies and who are facing a poor prognosis," Laura Carfang, executive director, SurvivingBreastCancer.org, said in the press release. "We need to combat this terrible disease, and all options that potentially slow its progress and extend life for those living with metastatic breast cancer are welcomed."

Click here for full prescribing information for Trodelvy.

Click here for more news about breast cancer.

Click here for a Cancer Health feature about antibody-drug conjugates.
