

FDA approves another chemotherapy alternative for aggressive form of breast cancer

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As of Wednesday, there's an FDA-approved treatment option besides chemotherapy for people with triple-negative breast cancer that has spread to other parts of the body.

New Jersey company Immunomedics got accelerated approval for Trodelvy, as a drug that fills a serious need and is adjudged "reasonably likely" to be beneficial. Though it passed a clinical trial with 108 patients with <u>metastatic breast cancer</u> , Trodelvy still needs to undergo more <u>clinical trials</u> to fully verify that it works.

"Metastatic triple-negative breast cancer is an aggressive form of breast cancer with limited treatment options. Chemotherapy has been the mainstay of treatment for triple-negative breast cancer," FDA Oncology Center of Excellence Director Dr. Richard Pazdur said in a statement.

Before taking Trodelvy, patients must have gone through two other treatments, the FDA said. That's likely by the very nature of <u>triple-negative breast</u> <u>cancer</u>, which the agency says accounts for 20%

of the worldwide breast cancer diagnoses.

"Triple-negative" breast cancer tests negative for three types of receptors, including human epidermal growth factor receptor 2 (HER2) protein, the approval announcement explains. That makes it invulnerable to hormonal therapy medicines or medicines that go after HER2.

Trodelvy goes after Trop-2, a receptor whose "expression in <u>cancer cells</u> has been correlated with drug resistance," according to a 2015 paper reposted by the National Center for Biotechnology Information. Trop-2 also often drives the metastasizing of breast cancer and prostate cancer.

Trodelvy does come with the FDA's most serious alert, a Boxed Warning or "black box warning." The warning is for abnormally low levels of white blood cells, which fight infection, and severe diarrhea.

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