

Antibody-guided drug shows encouraging activity in metastatic breast cancer

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A new antibody-drug compound shrank or halted the growth of metastatic breast tumors in almost half of a group of patients whose HER2-positive cancer had become resistant to standard therapies, according to early data from a multicenter Phase 2 clinical trial led by a Dana-Farber Cancer Institute researcher.

The findings will be presented at the 32nd annual CTRC-AACR San Antonio [Breast Cancer](#) Symposium on Saturday, Dec. 12.

Ian Krop, MD, PhD, principal investigator of the study, will report that the hybrid agent, called T-DM1, shrank tumors by 30 percent or more in 40 percent of women with confirmed HER2-positive cancers. Another 13 percent had stable disease for at least six months, for a total clinical benefit rate of approximately 53 percent. The median time before the disease progressed was 7.3 months, including both responders and non-responders. Patients received T-DM1 as long as it was effective and well-tolerated. A total of 110 women were enrolled in the study.

T-DM1 is comprised of the cell-killing drug DM1 and is chemically linked to the monoclonal antibody trastuzumab, which selectively binds to the HER2 growth signal receptor, which is highly overexpressed in HER2-positive breast tumors. Approximately 20 percent of breast cancers are HER2-positive.

Trastuzumab, developed by Genentech and sold under the name Herceptin, has markedly improved the treatment of HER2-positive cancer, but resistance to trastuzumab is a significant problem.

"The antibody binds to the [HER2 protein](#) on tumor cells and delivers the drug (DM1) selectively to them - but not to normal cells," Krop explained. "This allows us to deliver high doses of the chemotherapy directly to tumor cells. And at the same time, the antibody continues to block the

HER2 growth signals."

Krop said that one of the unique features of the study is that it is the first to address a population of women with metastatic HER2-positive breast cancer whose disease had progressed despite treatment with all of the FDA-approved drugs for this disease (trastuzumab, lapatinib and several chemotherapy agents).

On average, the women had metastatic breast cancer for three years and previously received seven different drugs for their cancer.

Although patients experienced side effects that included nausea, fatigue and lowered platelet counts, these effects were typically mild and the drug in general was well-tolerated, said Krop.

In addition to the current study, T-DM1 is being tested in larger Phase 3 trials comparing its effectiveness with that of other combined therapies.

Source: Dana-Farber Cancer Institute

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