

Genetech Seeks FDA Approval for New Breast Cancer Drug

The Burrill Report – Michael Fitzhugh
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Drug aimed at patients with recurrent cancer when Herceptin and other drugs have already been used.

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Genentech, a subsidiary of Roche, has submitted its new breast cancer drug to the FDA for approval, the company says, bringing a new option for women for whom other breast cancer drugs have proven ineffective much closer to market.

The drug, called trastuzumab-DM1, or T-DM1 for short, is designed to help women with advanced HER2-positive breast cancer who have previously received multiple HER2-targeted medicines and chemotherapies, including Genentech's Herceptin.

“While we've made great strides in treating HER2-positive breast cancer, there is a group of people whose breast cancer will come back after many treatments, leaving them with very limited options,” says Hal Barron, Genentech's executive vice president of global development and CMO.

A mid-stage study of the drug showed that it shrank tumors in women with HER2-positive breast cancer, a form of the malignancy in which the protein, human epidermal growth factor receptor 2, promotes the growth of cancer cells.

Now, as the FDA begins to review Roche's application for the drug, the company is beginning several mid-stage and late-stage trials to test how the drug stacks up to combination therapies that pair other drugs and courses of treatment, including one early access study in the United States for a small group of people.

Breast cancer is the second leading cause of cancer death among women in the United States, according to the American Cancer Society. Approximately 15 to 30 percent of cases are HER2-positive. In advanced HER2-positive cases, the cancer spreads to other parts of the body, most commonly to the lungs, bones, liver and brain.

Serving the pool of patients requiring treatment for the advanced form of the disease could generate more than \$1.8 billion (over CHF 2 billion) in sales for Roche, according to company estimates. Waltham, Massachusetts-based ImmunoGen, which licenses the technology behind T-DM1 under an agreement with Genentech, also stands to benefit if the new therapy is approved. Genentech is running approximately 50 early stages R&D programs for multiple tumor types involving the company's technology.