FDA Approves First Pre-Surgical Breast Cancer Drug

Matthew Perrone, AP Health Writer

A biotech drug from Roche has become the first medicine approved to treat breast cancer before surgery, offering an earlier approach against one of the deadliest forms of the disease.

The Food and Drug Administration approved Perjeta for women with a form of early-stage breast cancer who face a high risk of having their cancer spread to other parts of the body.

Surgery to remove tumors is usually the first step in treating most forms of cancer. Perjeta is the first drug to be approved as a pre-surgical step.

Doctors hope that using cancer drugs earlier could help shrink tumors, making them easier to remove. In some cases, that could allow women to keep their breasts, rather than having a full mastectomy. Doctors also say that treating the disease at its earliest stages could prevent tumors from returning later, though studies have not yet established that benefit.

"By making effective therapies available to high-risk patients in the earliest disease setting, we may delay or prevent cancer recurrences," said FDA's Dr. Richard Pazdur, who directs the agency's office of cancer products.
Cancer specialists already use several chemotherapy drugs as initial treatments for cancer, but they are not formally approved for the use. The FDA originally approved Perjeta to treat breast cancer that has spread to other parts of the body after surgery.

The FDA granted the drug accelerated approval for its new use based on a study showing women who received the drug as an initial treatment were more likely to be cancer-free 12 weeks later than women who received older drug combinations. Accelerated approval is reserved for drugs that show groundbreaking results for treating life-threatening diseases in early studies.

As a condition of approval, Roche's Genentech unit must conduct a larger follow-up study showing the drug's long-term benefits for patients. Generally that means showing that patients lived longer or had a higher quality of life due to taking the drug. Genentech, based in South San Francisco, Calif., has already enrolled about 4,800 patients in the follow-up study, with results expected in 2016.

Dr. Paula Klein, a breast cancer specialist, said she will start prescribing the drug for early-stage patients immediately, but stressed the importance of follow-up data on patient survival.

"This does not yet prove to us that using the antibody in this setting will result in more cures. That is still a hypothesis," said Klein, who directs the breast cancer program at Continuum Cancer Centers of New York.

The FDA said Monday's approval was based on a 417-woman study comparing Perjeta in different combinations against older breast cancer treatments. When Perjeta was combined with Herceptin, another Genentech drug, and standard chemotherapy, 39 percent of women saw their cancer reach undetectable levels. Only 21 percent of women experienced the same results from taking Herceptin and chemotherapy alone. After drug treatment all the women received standard breast surgery to remove any cancerous tumors. Genentech says this surgery allowed researchers to confirm the presence or absence of cancer.

Like Herceptin, Perjeta only works in a subset of about 20 percent of breast cancer patients who have tumors that overproduce a protein known as HER-2. This protein causes cancer cells to divide and grow faster than usual.
A spokeswoman for Genentech said a regimen of Perjeta plus Herceptin would cost between $27,000 and $49,000, depending on how long the patient takes the combination. The new Perjeta label will recommend a course of treatment between nine and 18 weeks.

Breast cancer is the second most deadly form of cancer in U.S. women, behind only lung cancer, and is expected to kill more than 39,000 Americans this year, according to the National Cancer Institute. About 6,000 to 8,000 deaths per year are attributed to the HER-2 form of the disease.

Breast cancer is highly treatable when detected early. More than 98 percent of women who are diagnosed with first-stage breast cancer survive at least five years, according to NCI figures.

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