Perjeta approved for advanced breast cancer

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(HealthDay) -- Perjeta (pertuzumab) has been approved by the U.S. Food and Drug Administration to treat people with HER2-positive late-stage breast cancer, the agency said in a news release.

HER2 is a protein involved in cell growth. Increased amounts of the protein, which tend to fuel cancer cell growth and survival, are found in about 20 percent of breast cancer cases, the FDA said.

Perjeta was approved for people who haven't been previously treated with an anti-HER2 therapy for metastatic (spreading) breast cancer, the agency said.

But the FDA warned that unspecified "production issues" facing manufacturer Genentech "could affect the long-term supply of the drug." The agency said the drug maker "has committed to take steps designed to resolve these production issues in a timely manner."

The drug's safety and effectiveness were evaluated in a clinical study of 808 people with HER2-positive breast cancer. The most common side effects noted were diarrhea, hair loss, a decrease in white blood cells, nausea, fatigue, rash and nerve damage.

The drug was approved with the agency's "black box" label warning of the potential for death or severe effects to a fetus. A woman's pregnancy status must be verified before she starts treatment with the drug, the FDA said.

San Francisco-based Genentech is a unit of the Roche Group.

More information: The FDA has more about this approval.