

Perjeta approved for advanced breast cancer

June 11 2012

(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](#).

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