FDA Grants Regular Approval to Perjeta for Adjuvant Treatment of HER2-Positive Breast Cancer

Adding Perjeta to adjuvant therapy reduces risk of post-surgery breast cancer recurrence.

December 20, 2017 By Food and Drug Administration (FDA)

On December 20, 2017, the Food and Drug Administration granted regular approval to pertuzumab (PERJETA, Genentech, Inc.) for use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

Approval was based on data from APHINITY (NCT01358877), a multicenter, randomized, double-blind, placebo-controlled trial in 4804 patients with HER2-positive early breast cancer who had their primary tumor excised prior to randomization. Patients were then randomized to receive pertuzumab or placebo, in combination with adjuvant trastuzumab and chemotherapy. The main efficacy outcome was invasive disease-free survival (IDFS), defined as the time from randomization to first occurrence of ipsilateral local or regional invasive breast cancer recurrence, distant recurrence, contralateral invasive breast cancer, or death from any cause.

After a median follow-up of 45.4 months, the proportion of IDFS events in the intent-to-treat population was 7.1% (n=171) in the pertuzumab arm and 8.7% (n=210) for those receiving placebo (HR 0.82; 95% CI: 0.67, 1.00; p=0.047). High-risk patients included patients such as those with hormone receptor negative or those with node positive breast cancer. The proportion of IDFS events in patients with hormone receptor negative disease was 8.2% (n=71) and 10.6% (n=91) in the pertuzumab and placebo arms, respectively (HR 0.76, 95% CI 0.56, 1.04). The proportion of IDFS events for patients with node positive disease was 9.2% (n=139) and 12.1% (n=181) in the pertuzumab and placebo arms, respectively (HR 0.77, 95% CI 0.62, 0.96). Overall survival data are not yet mature.

Adverse reactions reported in at least 30% of patients receiving pertuzumab in combination with trastuzumab and chemotherapy in APHINITY were diarrhea, nausea, alopecia, fatigue, peripheral neuropathy, and vomiting. The most common grade 3-4 adverse reactions (>2%) were neutropenia, febrile neutropenia, diarrhea, neutrophil count decreased, anemia, white blood cell count decreased, leukopenia, fatigue, nausea, and stomatitis.

The initial pertuzumab dose is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by 420 mg administered as a 30- to 60-minute intravenous infusion.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125409s113s118lbl.pdf.

In 2012, FDA granted regular approved to pertuzumab for use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

FDA granted accelerated approval to pertuzumab in 2013 as neoadjuvant treatment. With this latest adjuvant approval, the accelerated approval post-marketing requirement is fulfilled and regular approval is granted to pertuzumab for use in combination with trastuzumab and chemotherapy as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.

FDA granted priority review to pertuzumab for this application. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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