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Anti-Cancer Agent “PERJETA®,” Approved for Additional Indication of “Neoadjuvant and Adjuvant Therapy for HER2-Positive Early Breast Cancer”

TOKYO, October 10, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained a supplemental approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) on October 10, 2018, for the anti-cancer agent, pertuzumab (brand name: PERJETA® I.V. Infusion 420 mg/14 mL) for the indication of “neoadjuvant and adjuvant therapy for HER2-positive early breast cancer.” In Japan, PERJETA is currently on the market and its approved indication is in “HER2-positive inoperable or recurrent breast cancer.” With this supplemental approval, the indication of PERJETA has been broadened to “HER2-positive breast cancer.”

"The ultimate goal for early breast cancer treatment is to cure. Although treatment outcomes have improved over the years, unfortunately, some patients still have recurrence of cancer. By offering a new treatment option for HER2-positive early breast cancer with this approval, we hope that PERJETA can make an even greater contribution to the advancement of breast cancer treatments," said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "Chugai will continue to focus on collecting and providing information for the proper use of PERJETA against the treatment of HER2-positive breast cancer."

This approval is based on the results from the APHINITY study (**A**djuvant **P**ertuzumab and **H**erceptin **IN** **I**nitial **T**herap**Y** in Breast Cancer), a global phase III study, and several clinical studies. The APHINITY study is a global phase III study evaluating the efficacy and safety of PERJETA plus Herceptin and chemotherapy (anthracycline medicine followed by docetaxel or paclitaxel / docetaxel plus carboplatin) compared to Herceptin and chemotherapy as adjuvant (post-surgery) therapy in 4,805 patients (including 302 patients in Japan) with HER2-positive early breast cancer who have undergone curative surgery. The primary endpoint of the APHINITY study is invasive disease-free survival (IDFS), which is the time a patient lives without return of invasive breast cancer at any site or death from any cause after adjuvant therapy. PERJETA arm significantly reduced the risk of recurrence or death by 19% compared to control arm (HR=0.81, 95%CI 0.66-1.00, stratified log-rank test, p=0.0446). The safety profile of PERJETA was consistent with that seen in previous studies.

PERJETA was approved for neoadjuvant therapy for HER2-positive early breast cancer in September 2013 in the US and in July 2015 in Europe. In addition, PERJETA was approved for adjuvant therapy for HER2-positive early breast cancer in December 2017 in the US and in May 2018 in Europe.

As the leading pharmaceutical company in the field of oncology in Japan, Chugai believes that PERJETA will make a significant contribution to patients’ lives as a new treatment option for “HER2-positive early breast cancer.”

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

Drug Information

The underlined descriptions are newly added and changed.

Product name: PERJETA® I.V. Infusion 420 mg/14 mL

Generic name: pertuzumab (genetical recombination)

Indication: HER2-positive breast cancer

Dosage and administration:

The usual adult dosage when used in combination with trastuzumab (genetical recombination) and other anticancer drugs is a loading dose of 840 mg of pertuzumab (genetical recombination) followed by 420 mg every three weeks given by intravenous infusion over 60 minutes. For neoadjuvant or adjuvant chemotherapy, however, treatment should be given for up to 12 months. The infusion time can be shortened to as little as 30 minutes from the second infusion onward if the first infusion is well tolerated.

Drug price: PERJETA® I.V. Infusion 420 mg/14 mL JPY 238,491 / Vial