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Anti-Cancer Agent “Perjeta®” Filed for Additional Indication of Adjuvant Therapy for HER2-Positive Early Breast Cancer

TOKYO, October 25, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the approval of anti-HER2 humanized monoclonal antibody, "Perjeta® I.V. Infusion 420mg/14mL [generic name: pertuzumab (genetical recombination)] (hereafter, Perjeta)” for the additional indication of adjuvant therapy for HER2-positive early breast cancer.

"Currently, adjuvant chemotherapy with Herceptin® for HER2-positive early breast cancer has been recommended in the clinical practice guidelines for breast cancer and has contributed to patients," said Dr. Yasushi Ito, Chugai’s Senior Vice President, Head of Project & Lifecycle Management Unit. "We are going to continue discussions with the health authorities so that adjuvant chemotherapy using Perjeta in combination with Herceptin, which has outperformed the current standard of care, will be used as a new treatment option for patients."

Chugai filed the application with the MHLW based on the results from the APHINITY study (**A**djuvant **P**ertuzumab and **H**erceptin **IN** **I**nitial **T**herap**Y** in Breast Cancer) and several clinical studies. The APHINITY study is an international, phase III, randomised, double-blind, placebo-controlled, two-arm study evaluating the efficacy and safety of Perjeta plus Herceptin and chemotherapy (anthracycline medicine followed by docetaxel monotherapy / docetaxel plus carboplatin) compared to Herceptin and chemotherapy as adjuvant therapy in 4,805 patients with HER2-positive early breast cancer who undergone curative surgery. The primary endpoint of the APHINITY study is invasive disease-free survival (iDFS), which is defined as the time a patient lives without return of invasive breast cancer at any site or death from any cause after adjuvant treatment. The secondary endpoints were cardiac and overall safety, and other endpoints.

The results of the APHINITY study are as follows:

- At three years, iDFS, the primary endpoint, was 94.1% in the Perjeta arm and 93.2% in the control arm, and a statistically significant improvement was observed in the Perjeta arm. 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=0.045).
- The iDFS at four years estimated by the Kaplan-Meier method showed that 92.3% (95%CI: 91.1-93.4) of people treated with the Perjeta arm did not have their breast cancer return compared to 90.6% (95%CI: 89.3-91.8) treated with control arm.
- The safety profile of Perjeta was consistent with that seen in previous studies. The incidence of cardiac events was 0.7% in the Perjeta arm and 0.3% in the control arm.

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

In the US and Europe, Perjeta is under review for postoperative adjuvant chemotherapy for HER2-positive breast cancer, and the US Food and Drug Administration has granted Priority Review to Perjeta for this indication. Perjeta was approved for adjuvant therapy (before surgery) for HER2-positive early breast cancer in September 2013 in the US and in July 2015 in Europe.

As the top pharmaceutical company in the field of oncology in Japan, Chugai will work for early approval to provide Perjeta as a new treatment option for patients with HER2-positive early breast cancer.