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# Chugai Files for Additional Indication for Anti-HER2 Antibody Drug Conjugate Kadcyla for Adjuvant Therapy of HER2-Positive Early Breast Cancer

- Filing for additional indication for Kadcyla as an adjuvant therapy in patients with HER2-positive early breast cancer in Japan
- With this new indication, Chugai aims to further contribute to the treatment of HER2-positive early breast cancer by expanding upon HER2 franchise

TOKYO, August 30, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has filed an application to the Ministry of Health, Labour and Welfare (MHLW) in Japan for an additional indication for anti-HER2 antibody-tubulin polymerization inhibitor conjugate Kadcyla® (generic name: trastuzumab emtansine), as adjuvant therapy in patients with HER2-positive early breast cancer.

“There is still a high unmet medical need for the development of treatment methods when pathologic complete response (pCR) is not obtained by neoadjuvant therapy. This application is the first step in providing patients with Kadcyla as a new treatment option of adjuvant therapy,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “Our HER2 franchise, consisting of Herceptin®, Perjeta® and Kadcyla has contributed to improving the outcomes of HER2-positive breast cancer. In this indication, we will continue to discuss with the regulatory authorities for the early approval of Kadcyla.”

This application is based on results from an open-label, randomized, global phase III clinical study (the KATHERINE study), evaluating efficacy and safety of Kadcyla adjuvant therapy compared to Herceptin in almost 1,500 people with HER2-positive early breast cancer who had invasive residual disease in the breast and/or axillary lymph nodes following neoadjuvant therapy including Herceptin. The primary endpoint of the study was invasive disease-free survival (IDFS) Based on the results of the study, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to Kadcyla as adjuvant therapy and gave regulatory approval on May 3, 2019, which is just over 12 weeks after submission under the FDA’s Real-Time Oncology Review pilot program.

The main results from the KATHERINE study are as follows:

- According to the first interim analysis of the primary endpoint, the superiority of Kadcyla over Herceptin in IDFS has been confirmed (unstratified hazard ratio: 0.50 [95% confidence interval: 0.39-0.64, log-rank test, $p<0.0001$].
- No superiority of Kadcyla over Herceptin in overall survival was observed in the first interim analysis of the secondary endpoint conducted at the same time.
- Adverse events were observed in 731 patients (98.8%) in Kadcyla group, which was consistent with

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the safety profile of Kadcyla in patients with HER2-positive metastatic breast cancer. Kadcyla as an adjuvant therapy was also well tolerated in patients with HER2-positive early breast cancer.

As a leading company in the field of oncology, Chugai will work to obtain approval for the additional indication to further contribute to the treatment of HER2-positive breast cancer.

[Reference information]
Media release issued by Roche on May 6, 2019
Title: FDA approves Roche's Kadcyla for adjuvant treatment of people with HER2-positive early breast cancer with residual invasive disease after neoadjuvant treatment
https://www.roche.com/media/releases/med-cor-2019-05-06.htm



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