



## Chugai Obtains Approval for Additional Indication of Kadcyla for Adjuvant Therapy of HER2-Positive Early Breast Cancer

- Kadcyla obtained an additional indication of HER2-positive postoperative early breast cancer, in addition to the indication of HER2-positive inoperable or recurrent breast cancer.
- Kadcyla is a postoperative new treatment option to improve prognosis in the treatment of HER2-positive early breast cancer when pathologic complete response (pCR) is not obtained by neoadjuvant therapy.

TOKYO, August 21, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it has obtained approval for anti-HER2 antibody-tubulin polymerization inhibitor conjugate Kadcyla<sup>®</sup> Intravenous Infusion 100 mg and 160 mg [generic name: trastuzumab emtansine (genetical recombination)] from the Ministry of Health, Labour and Welfare for an additional indication of HER2-positive postoperative breast cancer.

“It is said that the prognosis is poor when pathologic complete response (pCR) is not obtained by neoadjuvant therapy in the treatment of HER-2 positive early breast cancer. In the KATHERINE study, which was evaluated for regulatory approval, Kadcyla reduced the risk of invasive breast cancer recurrence or death from any cause by 50% compared to Herceptin. We are very pleased that this approval addresses an unmet medical need for patients seeking a cure, and contributes to the advancement of treatment,” said Dr. Osamu Okuda, Chugai’s President and COO. “As a leading company in the field of oncology, Chugai will strive to promote the appropriate use of this treatment for the benefit of patients.”

This approval is based on the results from an open-label, randomized, global phase III KATHERINE study. The study evaluated the efficacy and safety of Kadcyla adjuvant therapy in 1,486 patients with HER2-positive early breast cancer who did not have pathologic complete response following neoadjuvant therapy including Herceptin. The results confirmed the superiority of Kadcyla over Herceptin in terms of the primary endpoint of invasive disease-free survival (unstratified hazard ratio: 0.50 [95% confidence interval: 0.39-0.64, log-rank test, p<0.0001]). The safety profile of Kadcyla in this study was consistent with those observed in the previously approved treatment of HER2-positive metastatic breast cancer, and Kadcyla was also well-tolerated as an adjuvant treatment in HER2-positive early breast cancer.

### Reference

Chugai Files for Additional Indication for Anti-HER2 Antibody Drug Conjugate Kadcyla for Adjuvant Therapy of HER2-Positive Early Breast Cancer (Press release issued on August 30, 2019)

[https://www.chugai-pharm.co.jp/english/news/detail/20190830150000\\_636.html](https://www.chugai-pharm.co.jp/english/news/detail/20190830150000_636.html)

**Prescribing Information** \*The underlined parts were newly added.

Product name:	Kadcyla® Intravenous Infusion 100 mg Kadcyla® Intravenous Infusion 160 mg
Generic name:	trastuzumab emtansine (genetical recombination)
Indications:	<ul style="list-style-type: none"> <li>• HER2-positive inoperable or recurrent breast cancer</li> <li>• <u>HER2-positive postoperative breast cancer</u></li> </ul>
Precautions concerning indications:	<p><u>&lt;All Indications&gt;</u></p> <ol style="list-style-type: none"> <li>1. HER2 testing should be conducted by a pathologist or testing facility with the necessary experience.</li> <li><u>2. Administer Kadcyla to patients who have already received trastuzumab (genetical recombination) and chemotherapy with a taxane antineoplastic agent.</u></li> <li><u>3. The efficacy and safety of Kadcyla in pre-operative drug treatment have not been established.</u></li> </ol> <p><u>&lt; post-operative drug treatment in HER-2 positive Breast Cancer &gt;</u></p> <ol style="list-style-type: none"> <li><u>4. This drug should be used for patients for whom a pathological complete response (pCR) has not been obtained by pre-operative drug treatment.</u></li> <li><u>5. Select Kadcyla-eligible patients based on a thorough understanding of the efficacy and safety of Kadcyla by carefully reviewing the definition of pCR and other relevant information for patients enrolled in the clinical studies described in "17. CLINICAL STUDIES."</u></li> </ol>
Dosage and administration:	<ul style="list-style-type: none"> <li>• The usual adult dosage is 3.6 mg/kg (body weight) trastuzumab emtansine (genetical recombination) administered by intravenous infusion every 3 weeks. <u>However, in the case of post-operative breast cancer drug treatment, the number of doses is up to 14 times.</u></li> </ul>

### About Kadcyla

Kadcyla is an antibody-drug conjugate. It comprises of the anti-HER2 humanized monoclonal antibody, trastuzumab, and a chemotherapeutic drug, DM1, attached together using a stable linker. Kadcyla is designed to target HER2, inhibit HER2 signaling, induce antibody-dependent cell mediated cytotoxicity, and deliver the chemotherapeutic drug DM1 directly inside HER2-positive cancer cells. Once Kadcyla is taken up by those cancer cells, it is designed to destroy them by the DM1. Kadcyla was approved for the adjuvant treatment of patients with HER2-positive early breast cancer with residual invasive disease after neoadjuvant treatment in the U.S. in May 2019 and in EU in December 2019.

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