CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL:+81-(0)3-3273-0881
FAX:+81-(0)3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agent, Antibody Drug Conjugate "Kadcyla®" Postponement of Price Listing on the NHI Reimbursement List and Implementation of a New Clinical Study

November 13, 2013 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that the price listing of anti-HER2 antibody - tubulin polymerization inhibitor conjugate, "Kadcyla® Intravenous Infusion 100 mg and 160 mg" [generic name: trastuzumab emtansine (genetical recombination)] (hereafter, Kadcyla®) on the National Health Insurance reimbursement list in November will be postponed. Kadcyla® was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) on September 20, 2013, for "HER2-positive inoperable or recurrent breast cancer," and Chugai has been preparing to have the price of Kadcyla® listed in November.

Chugai has decided to implement a new clinical study, although with certain restrictions, in order to provide eligible patients in Japan with the opportunity to benefit from treatment with Kadcyla® until the launch of the product. Further clinical data on Japanese patients will also be collected in the study. The new trial is scheduled to start with medical institutions that have finalized the necessary procedures and is planned to continue until the price of Kadcyla® is listed and the product is launched. Currently, preparations to start the trial are on-going, and the details will be announced in January 2014. The trial will be open to patients with "HER2-positive inoperable or recurrent breast cancer," the approved indication of the product, who have cleared certain participation criteria. The trial is expected to sequentially start around late January 2014 and Chugai is planning to cover every prefecture in Japan by at least one institution.

Chugai strongly believes that Kadcyla® can contribute to the treatment of patients with "HER2-positive inoperable or recurrent breast cancer" by providing a new therapeutic option, and continues its effort for an early launch to make this significant innovation available to patients in Japan.

About Kadcyla® [trastuzumab emtansine (T-DM1)]

Kadcyla® is a conjugate of antibody trastuzumab and chemical compound 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 chemotherapy DM1 directly inside HER2-positive cancer cells. Once Kadcyla® is taken up by those cancer cells, it is designed to destroy them by releasing the DM1.

It is confirmed by the global phase III clinical trial (EMILIA study) that Kadcyla® demonstrates superior efficacy and safety by selectively targeting cancer cells, extending survival compared to existing treatments. The most frequent adverse events for patients of Grade 3 or over receiving Kadcyla® were decrease in platelets, increase in AST and ALT, etc.