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CHUGAI
Roche Roche Group

Translation

Launch of the Anti-Cancer Agent "Kadcyla®"

April 17, 2014 (Tokyo) – Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it will launch the anti-HER2 antibody-tubulin polymerization inhibitor conjugate "Kadcyla® Intravenous Infusion 100 mg and 160 mg" [generic name: trastuzumab emtansine (genetic recombinant)] (hereafter, Kadcyla®) for the indication of "HER2-positive inoperable or recurrent breast cancer" on April 18, 2014. Kadcyla® received a manufacturing and marketing approval on September 20, 2013 and was listed on the National Health Insurance (NHI) reimbursement price list on April 17, 2014.

Kadcyla® is a recombinant humanized monoclonal antibody developed by F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan] (hereafter, Roche), a global pioneer and leader in Personalised Healthcare. Kadcyla® is an antibody drug conjugate, comprising the anit-HER2 humanized monoclonal antibody, trastuzumab, and a cytotoxic tubulin polymerization inhibitor, DM1, attached together using a stable linker. Kadcyla® is designed to target HER2, thereby inhibiting HER2 signaling and inducing antibody-dependent cell mediated cytotoxicity, and at the same time the tubulin polymerization inhibitor DM1 is directly delivered inside the HER2-positive cancer cells to destroy them.
Kadcyla® was approved for patients with previously treated, HER2-positive metastatic breast cancer in the US in February 2013 and in Europe in November 2013.

The number of patients newly diagnosed with breast cancer in Japan continues to rise each year and is estimated to become, on annual average, approximately 60,000 during 2015-2019*. And HER2 expression has been observed in approximately 20% of breast cancer patients.

Following the approval of Kadcyla® in September 2013, in order to provide access to patients, Chugai initiated a clinical study at a limited number of medical institutions from January 2014. The purpose of the study was to accumulate Japanese clinical data. Since enrollment has reached the target number and access will be normalized after launch, this study will be terminated and the data will be compiled.

As the top pharmaceutical company in the field of oncology in Japan, Chugai is convinced that Kadcyla® can contribute to the treatment of patients with "HER2-positive inoperable or recurrent breast cancer" by providing a new therapeutic option and will promote appropriate use of Kadcyla®.

* T. Sobue, et al., Cancer White Paper 2012, Shinoharashinsha Inc.

Drug Information

Brand name:	Kadcyla® Intravenous Infusion 100 mg Kadcyla® Intravenous Infusion 160 mg	
Generic name:	trastuzumab emtansine (genetical recombination)	
Indications:	HER2-positive inoperable or recurrent breast cancer	
Dosage and administration:	The usual adult dosage is 3.6 mg/kg (body weight) of trastuzumab emtansine (genetical recombination) every three weeks given by intravenous infusion.	
Date of approval:	September 20, 2013	
Date of listing in the NHI reimbursement price:	April 17, 2014	
Date of launch:	April 18, 2014	
Shelf life:	Kadcyla® Intravenous Infusion 100 mg	2 years and 6 months
	Kadcyla® Intravenous Infusion 160 mg	3 years
Drug price:	Kadcyla® Intravenous Infusion 100 mg/vial	235,108 yen
	Kadcyla® Intravenous Infusion 160 mg/vial	373,945 yen

Kadcyla® is a registered trademark of F. Hoffmann-La Roche, Ltd.

Package photo