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CHUGAI
Roche Group

Translation

Launch of the Anti-Cancer Agent "Perjeta®"

September 12, 2013 (Tokyo) – Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it launched the anti-cancer agent "Perjeta® I.V. Infusion 420mg/14mL" [generic name: pertuzumab (genetic recombinant)] (hereafter, Perjeta®) for the indication of "HER2-positive inoperable or recurrent breast cancer" on September 12. Perjeta® received a manufacturing and marketing approval on June 28, 2013 and was listed on the National Health Insurance (NHI) reimbursement price list on August 27, 2013.

Perjeta® 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. Perjeta® targets HER2, a same target of trastuzumab, a treatment for breast cancer developed by Roche. In HER2-positive breast cancer patients, HER2 exists in large amount on the surface of cancer cells and sends out proliferation signals to cells.

Perjeta® is believed to work in a way that is complementary to Herceptin, as the two medicines target different regions on the HER2 receptor. Perjeta® is a first-in-class HER2 Dimerisation Inhibitor (HDI) monoclonal antibody. The combination of Perjeta® and trastuzumab together provides a more comprehensive blockade of HER signaling pathways than either agent alone. Perjeta® works by binding to HER2 to prevent HER2 from making pairs with HER3 or other types of HER which also sends proliferation signals when making pairs with HER2. In addition, Perjeta® and/or trastuzumab binding to HER2 draw immune cells (macrophage or NK cells) to attack and kill cancer cells by the activation of antibody dependent cellular cytotoxicity.

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.

As the top pharmaceutical company in the field of oncology, Chugai is convinced that Perjeta® 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 Perjeta®.

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

Drug Information

Brand name:	Perjeta® I.V. Infusion 420mg/14mL
Generic name:	pertuzumab (genetic recombinant)
Indications:	HER2-positive inoperable or recurrent breast cancer
Dosage and administration:	The usual adult dosage when used in combination with trastuzumab (genetic recombinant) and other anticancer drugs is a loading dose of 840 mg of pertuzumab (genetic recombinant) followed by 420 mg every three weeks given by intravenous infusion over 60 minutes. The infusion time can be shortened to as little as 30 minutes from the second infusion onward if the first infusion is well tolerated.
Date of approval:	June 28, 2013
Date of listing in the NHI reimbursement price:	August 27, 2013
Date of launch:	September 12, 2013
Shelf life:	2 years
Drug price:	Perjeta® I.V. Infusion 420mg/14mL vial 231,866 yen

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

Package photo