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Chugai Launches Phesgo Subcutaneous Combination for the Treatment of HER2-Positive Breast and Colorectal Cancer

- Chugai launches Phesgo, a subcutaneous combination of pertuzumab and trastuzumab (the monoclonal antibodies contained in Perjeta and Herceptin), for the treatment of HER2-positive breast and colorectal cancer
- Phesgo can be administered over 5-8 minutes, compared to the conventional intravenous infusion, which is administered over 60-150 minutes
- The first subcutaneous injection for HER2-positive colorectal cancer in the world
- Perjeta and Herceptin are standard therapy for HER2-positive breast cancer

TOKYO, November 22, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it launched Phesgo® combination for Subcutaneous Injection MA, IN [generic name: pertuzumab (genetical recombination), trastuzumab (genetical recombination) and vorhyaluronidase alfa (genetical recombination)] (hereafter, Phesgo), antineoplastic agent / anti-HER2 humanized monoclonal antibody for the treatment of “HER2-positive breast cancer” and “Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection.” Phesgo had been approved by the Ministry of Health, Labour and Welfare (MHLW) on September 25, 2023 and was listed on the national health insurance (NHI) reimbursement price list today.

“We are very pleased to launch Phesgo in Japan, a fixed-dose combination for subcutaneous use containing the same anti-HER2 agents of Perjeta® and Herceptin®, the standard therapy for HER2-positive breast cancer. Phesgo is a drug that can be administered in a shorter time than conventional intravenous injections. As lifestyles and social environments diversify, shortening infusion time is expected to improve patients' daily lives. In addition, since it is the fixed-dose subcutaneous injection that does not require preparation, it is expected to contribute to the efficiency of medical resources. With Phesgo as a new treatment option, we will work to promote its proper use so that we can deliver unprecedented value to patients undergoing cancer treatment in various settings, their families, and healthcare providers,” said Dr. Osamu Okuda, Chugai's President and CEO.

Phesgo, this subcutaneous fixed-dose combination without preparation contains the same monoclonal antibodies as Perjeta and Herceptin, and also a vorhyaluronidase alfa (genetical recombination) combined in a single vial. It takes over eight minutes for a loading dose of Phesgo and over five minutes for the subsequent doses. By comparison, it takes 150 minutes for a sequential infusion of a loading dose of Perjeta and Herceptin using intravenous formulations (excluding follow-up observation), and 60-150* minutes for the subsequent maintenance dose infusions.[1,2,3)]

*Both drugs can be shortened to 30 minutes if the initial administration is well tolerated

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

The regulatory approval is based on the results of the global phase III FeDeriCa study including Japan and an overseas phase II PHranceSCa study. FeDeriCa study evaluated the pharmacokinetics, efficacy, and safety of Phesgo with patients with HER2-positive breast cancer. PHranceSCa study examined patient preference and satisfaction with subcutaneous administration of Phesgo in HER2-positive breast cancer.

[Approval Information]
Product name: PHESGO® combination for Subcutaneous Injection MA, IN
Generic name: pertuzumab (genetical recombination), trastuzumab (genetical recombination) and vorhyaluronidase alfa (genetical recombination)
Indications:

- HER2-positive breast cancer
- Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection

Dosage and administration:

< HER2-positive breast cancer >

The usual adult dosage is an initial dose of 1200 mg, 600 mg, and 30000 U of pertuzumab (genetical recombination), trastuzumab (genetical recombination), and vorhyaluronidase alfa (genetical recombination), respectively, administered subcutaneously over 8 minutes, followed by 600 mg, 600 mg, and 20000 U of the second and subsequent doses over 5 minutes every 3 weeks thereafter, in combination with other antineoplastic agents. For neoadjuvant or adjuvant therapy, the duration of treatment should be up to 12 months.

< Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection >

The usual adult dosage is an initial dose of 1200 mg, 600 mg, and 30000 U of pertuzumab (genetical recombination), trastuzumab (genetical recombination), and vorhyaluronidase alfa (genetical recombination), respectively, administered subcutaneously over 8 minutes, followed by 600 mg, 600 mg, and 20000 U of the second and subsequent doses over 5 minutes every 3 weeks thereafter.

Date of approval: September 25, 2023
Date of NHI reimbursement price listing: November 22, 2023
Date of launch: November 22, 2023
Drug price: PHESGO® combination for Subcutaneous Injection MA JPY 268,695 / bottle, IN JPY 471,565 / bottle

[Reference]
Chugai Obtains Regulatory Approval for Phesgo, the Fixed-Dose Subcutaneous Combination of Perjeta and Herceptin for HER2-Positive Breast and Colorectal Cancer (Press release issued on September 25, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20230925150001_1007.html

About Phesgo (Pertuzumab, Trastuzumab and vorhyaluronidase alfa)
Phesgo, the fixed-dose subcutaneous combination contains the same monoclonal antibodies as Perjeta, Herceptin, and vorhyaluronidase alfa (genetical recombination) in a single vial. Hyaluronidase, an enzyme that breaks down hyaluronic acid, is considered to increase dispersion and absorption of the antibodies

using Halozyme Therapeutics' Enhanze® drug delivery technology.[4] The monoclonal antibodies in Phesgo are identical to those in Perjeta and Herceptin. The mechanisms of action of Perjeta and Herceptin are believed to complement each other as both bind to the HER2 receptor, but in different locations.[5,6] The combination of Perjeta and Herceptin is thought to provide a more comprehensive, dual blockade of the HER signaling pathways.[5,6]

About FeDeriCa study[7]

FeDeriCa study is an international, multi-center, two-arm, randomized, open-label, phase III study evaluating the pharmacokinetics, efficacy and safety of subcutaneous injection of the fixed-dose combination of Perjeta and Herceptin in combination with chemotherapy, compared with standard intravenous infusions of Perjeta and Herceptin in combination with chemotherapy in 500 people with HER2-positive early breast cancer who are being treated in the neoadjuvant (before surgery) and adjuvant (after surgery) settings. The primary endpoint of the study is minimum levels of Perjeta in the blood during a given dosing interval (C_{trough}). Secondary endpoints include safety; minimum levels of Herceptin in the blood during a given dosing interval (C_{trough}); and pathological complete response (pCR) in the breast and axilla.

About PHranceSCa study[8]

PHranceSCa study is an overseas phase II randomized clinical study to evaluate patient preference and satisfaction for the fixed-dose combination of Perjeta and Herceptin for subcutaneous injection in 160 patients with HER2-positive early breast cancer. The primary endpoint is patient's preference for this drug based on responses to the Patient Preference Questionnaire (PPQ). Secondary endpoints include patient satisfaction with this drug and Perjeta and Herceptin intravenous formulations as measured by the Therapy Administration Satisfaction Questionnaire (TASQ), and patient's selection of this drug during continued treatment.

Sources

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