Category

Best Pharmaceutical Product

General Information

Company Name *

Genentech, A Member of the Roche Group

Product/Solution Name *

PHESGO - Fixed-Dose Combination of Perjeta and Herceptin for Subcutaneous Injection for HER2-Positive Breast Cancer

Compound/Tech Name*

Fixed-dose combination (FDC) of Perjeta® (pertuzumab) and Herceptin® (trastuzumab) with ENHANZE® (Halozyme's proprietary hyaluronidase), administered by subcutaneous (SC, under the skin) injection

Trade Name *

PHESGO

Corporate Name *

PHESGO

Date of Approval *

2020-06-29

Indications *

PHESGO (pertuzumab, trastuzumab, and hyaluronidase) is a prescription medicine approved for use in combination with chemotherapy for:
use prior to surgery (neoadjuvant treatment) in adults with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (tumour is greater than 2 cm in diameter or node-positive). PHESGO should be used as part of a complete treatment regimen for early breast cancer.
use after surgery (adjuvant treatment) in adults with HER2-positive early breast cancer that has a high likelihood of coming back.

PHESGO is also approved for use in combination with docetaxel in adults who have HER2-positive breast cancer that has spread to different parts of the body (metastatic) and who have not received anti-HER2 therapy or chemotherapy for metastatic breast cancer.

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Therapeutic Areas *

fixed-dose combination, subcutaneous administration, breast cancer treatment, HER2-positive breast cancer, innovation

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*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

World's first fixed dose combination of two monoclonal antibodies in oncology for the treatment of HER-2 positive breast cancer that can be administered by a single subcutaneous injection.

PHESGO (subcutaneous Perjeta and Herceptin) is a fixed-dose formulation of Perjeta and Herceptin with Halozyme Therapeutics' ENHANZE® drug delivery technology.
Trastuzumab in PHESGO is the same monoclonal antibody as in IV Herceptin and pertuzumab in PHESGO is the same monoclonal antibody as in IV Perjeta. The mechanisms of action of Perjeta and Herceptin are believed to complement each other, as both bind to the HER2 receptor, but to different places. The combination of Perjeta and Herceptin is thought to provide a more comprehensive, dual blockade of HER signalling pathways, thus preventing tumour cell growth and survival.
Halozyme's proprietary ENHANZE® drug delivery technology can enable and optimise the SC drug delivery co-administered therapeutics. The technology is based on a patented recombinant human hyaluronidase PH20 (rHuPH20) enzyme that locally degrades hyaluronan - a glycosaminoglycan or chain of natural sugars in the body, to transiently aid in the dispersion and absorption of other injected therapeutic drugs.
This innovative approach leads to- a series of benefits, including:
Effective HER2+ BC treatment in minutes, not in hours
Significant time savings for patients and HCPs (freeing up to 70% of active HCP and patient time)
Minimised pressure on healthcare systems by allowing more flexibility in preparation, reducing preparation and administration time as well as other costs associated with treatment, such as time spent in the infusion chair and optimising patient care
Preferred by patients both in terms of comfort and speed of treatment, e.g. time required in the clinic

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History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

About the FeDeriCa study
FeDeriCa was an international, multi-center, two-arm, randomised, open-label, Phase III study evaluating the pharmacokinetics, efficacy, and safety of SC injection of PHESGO in combination with chemotherapy, compared with standard IV infusion of Perjeta and Herceptin in combination with chemotherapy, in 500 people with HER2-positive EBC who were being treated in the neoadjuvant (before surgery) and adjuvant (after surgery) settings. The primary endpoint of the study was minimum levels of Perjeta in the blood during a given dosing interval (Ctrough). Secondary endpoints

include safety; minimum levels of Herceptin in the blood during a given dosing interval (Ctrough); and total pathological complete response, meaning there was no tumour tissue detectable in the tissue removed at the time of surgery. The FeDeriCa study met its primary endpoint of non-inferior levels of Perjeta in the blood. The geometric mean ratio (GMR; a type of average used when assessing pharmacokinetics) for the primary endpoint was 1.22 (90% CI: 1.14 to 1.31), with the lower limit of the 90% CI of the GMR=1.14≥0.80 (the pre-specified non-inferiority margin). A secondary endpoint of non-inferior levels of Herceptin was also met, with blood concentrations for people receiving the fixed-dose combination non-inferior to those receiving IV Herceptin (GMR=1.33 [90% CI: 1.24 to 1.43]; lower limit of 90% CI of GMR=1.24≥0.80). A non-inferiority endpoint was chosen for the study to ensure that people were receiving sufficient dosing with Perjeta and Herceptin as compared to the established IV doses at the same treatment intervals.
The tpCR rate of PHESGO (59.7%) was nearly identical to that of P + H IV (59.5%) and consistent with previous data from trials with P + H + chemotherapy
Long-term efficacy of PHESGO was comparable to that of P + H IV for all efficacy parameters (IDFS, EFS, DRFI, OS)
The safety profile of PHESGO was comparable with that of Perjeta and Herceptin administered intravenously.

About the PHranceSCa study
PHranceSCa was a randomised, multi-center, multinational, open-label, cross-over Phase II study evaluating patient preference for and satisfaction with subcutaneous (SC) administration of PHESGO. All patients completed neoadjuvant treatment with Perjeta, Herceptin and chemotherapy and had surgery before randomization. The primary endpoint of the study was the percentage of participants who indicated that they prefer treatment with PHESGO compared to the standard intravenous (IV) formulations of Perjeta and Herceptin. Secondary endpoints include participant-reported satisfaction and health-related quality of life outcomes; healthcare professionals' perceptions of time and resource use and convenience compared with IV formulations; as well as the safety and efficacy of each study regimen.
Of the 160 patients that were randomised, 136 (85.0%, 95%CI: 78.5-90.2%) preferred PHESGO; 22 (13.8%) preferred PH IV; 2 (1.3%) had no preference. The main reasons for SC preference were reduced clinic time (n = 119) and comfort during administration (n = 73). 141 patients (88.1%) were very satisfied/satisfied with SC injection versus 108 (67.5%) with IV infusion. PHESGO was generally well tolerated, with no new safety signals (even when switching), and offers a quicker alternative to IV infusion.

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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

PHESGO is the first in oncology to combine two monoclonal antibodies in one single-dose vial administered subcutaneously which allows significant time and resource savings. PHESGO administration takes approximately 5-8 minutes. This is compared to approximately 60-150 minutes for infusions with Perjeta and Herceptin using the standard IV formulations.
PHESGO offers a treatment administration that has the patient experience in mind which was proven by the 85% patient preference in comparison to IV. It supports the needs and preferences of individual

patients, and helps to meet the increasing demand across the healthcare system for faster and more flexible treatment options.
PHESGO minimises patient time in office which is and continues to be especially important not only during times of global pandemics to minimise chances of patient exposure. With growing healthcare worker shortages in many countries, PHESGO offers HCPs a chance to efficiently serve patients and potentially frees up chair time for other oncology patients that need care.
Since launch, over 60,000 patients in more than 100 countries have benefited from treatment with PHESGO worldwide.
Not only have we seen examples of time savings in the hospital with PHESGO, we have also seen a shift in cancer care where PHESGO is offered outside of the hospital (flexible care) i.e. in patient's homes, mobile clinics, satellite clinics. This is the future of cancer care, where patients can have a choice in where their treatment will be received and not defined by cancer.

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Please provide appropriate references (PubMed, Abstract, Website) *

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