PHESGO®
pertuzumab/trastuzumab/hyaluronidase-zzxf
SUBCUTANEOUS INJECTION / 1,200 mg/600 mg/30,000 units
600 mg/600 mg/20,000 units

Click to see data from a TIME & MOTION STUDY

For your eligible patients with HER2+ breast cancer,

PHESGO gives the opportunity to **save time for your patients and practice**[1]

PHESGO is a fixed-dose subcutaneous treatment with PERJETA® (pertuzumab) and trastuzumab that's administered in **~5 minutes**.*[1]

*Refers to actual PHESGO injection time of ~5 minutes for the maintenance dose. **The loading dose is ~8 minutes.** This does not account for observation time and other aspects of treatment. Actual clinic time may vary.[1]

PHESGO is FDA approved for all of the same HER2+ breast cancer indications as PERJETA.[1,2]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) state that pertuzumab, trastuzumab, and hyaluronidase-zzxf injection for subcutaneous use **(PHESGO) may be substituted anywhere that IV pertuzumab (PERJETA) + trastuzumab are given** as part of systemic therapy for HER2+ breast cancer.†[3]

†Pertuzumab, trastuzumab, and hyaluronidase-zzxf injection for subcutaneous use (PHESGO) have different dosing and administration instructions compared to the intravenous products.

HER2=human epidermal growth factor receptor 2.

Indications

Early Breast Cancer

PHESGO is indicated for use in combination with chemotherapy for

- the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node-positive) as part of a complete treatment regimen for early breast cancer (EBC)
- the adjuvant treatment of adult patients with HER2-positive early breast cancer (EBC) at high risk of recurrence

Select patients for therapy based on an FDA-approved companion diagnostic test.

Metastatic Breast Cancer

PHESGO is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Select patients for therapy based on an FDA-approved companion diagnostic test.

Important Safety Information

BOXED WARNINGS: Cardiomyopathy, Embryo-Fetal Toxicity, and Pulmonary Toxicity

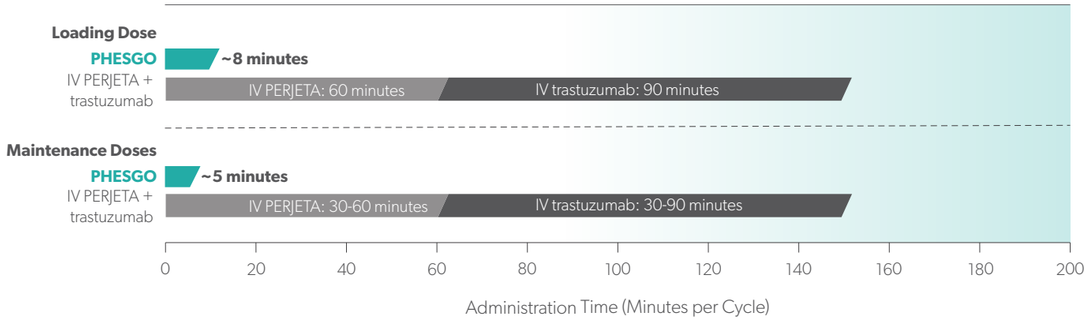
- **PHESGO administration can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving PHESGO with anthracycline-containing chemotherapy regimens. Evaluate cardiac function prior to and during treatment with PHESGO. Discontinue PHESGO treatment in patients receiving adjuvant therapy and withhold PHESGO in patients with metastatic disease for clinically significant decrease in left ventricular function**
- **Exposure to PHESGO can result in embryo-fetal death and birth defects, including oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception**
- **PHESGO administration can result in serious and fatal pulmonary toxicity. Discontinue PHESGO for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Monitor patients until symptoms completely resolve**

Please see Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNINGS.

You May **Save Substantial Time** for Your Patients and Practice With **PHESGO**[1,2,4]

PHESGO is a faster treatment option for your patients and practice[1,2]

Faster administration with PHESGO vs IV PERJETA + IV trastuzumab*[1,2]



- **Patients should be observed for a minimum of 30 minutes after initial dose of PHESGO and 15 minutes after each maintenance dose of PHESGO** for signs of hypersensitivity symptoms or administration-related reactions. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use

*Refers to actual injection time of PHESGO vs infusion time of IV PERJETA + trastuzumab and does not account for all aspects of treatment. Actual clinic time may vary. PERJETA and trastuzumab can be given in any order.[1,2] Please see the PERJETA full Prescribing Information for additional dosing information for PERJETA + trastuzumab.

Fixed-dose PHESGO requires[1]:

NO reconstitution	**NO** dilution	**NO** weight adjustments	**NO** IV loading dose	**NO** port access with a subcutaneous injection

An opportunity to give your patients & practice **more time back with PHESGO**[1,2]

Observed Times of PHESGO vs IV PERJETA + IV trastuzumab in a Time & Motion Study[4]

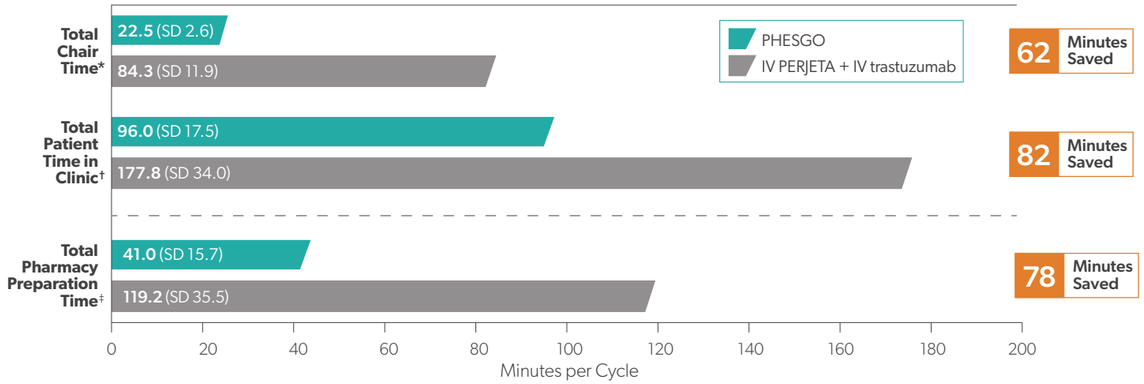
Time & Motion Study Design

- The Time & Motion study is a prospective, pre-specified substudy of ADEPT. ADEPT is a single-arm Phase 2 study of patients with HER2+ early breast cancer. The Time & Motion study enrolled 22 patients after their initial loading dose of PHESGO
- Each patient in the Time & Motion study received 4 maintenance doses: 2 cycles of IV PERJETA + IV trastuzumab followed by 2 cycles of PHESGO (88 total cycles evaluated)
- **Study objective:** Estimate the relative difference in time and logistical burden between IV PERJETA + IV trastuzumab and PHESGO
  - **Primary endpoint:** Patient chair time
  - **Secondary exploratory endpoints:** Patient time in clinic, drug administration time, pharmacy drug preparation time

Time & Motion Study Limitations and Considerations

- Performed at a single US institution (Dana Farber Cancer Institute). Results may not be generalizable to other centers
- Protocol allowed for shorter observation time after IV PERJETA administration than specified in the PERJETA USPI
- Evaluated maintenance doses only and did not review differences in loading dose times

PHESGO time savings for HCPs, patients, and pharmacists vs IV PERJETA + IV trastuzumab[4]



*Patients were evaluated from the start of first drug administration to the end of the final post-drug observation period.
†Patients were evaluated from the infusion room check-in time to the end of the final post-drug observation period. Administration time was also studied and is a component of the chair time and total patient time in clinic endpoints.
‡Total pharmacy prep time was evaluated from order receipt by pharmacy to drug leaving the pharmacy.

In this Time & Motion study,
treating patients with PHESGO took on average less than a third of the chair time needed to treat with IV PERJETA + IV trastuzumab[4]

What could this time savings mean for your patients and practice?

Important Safety Information (cont'd)

Contraindications

PHESGO is contraindicated in patients with known hypersensitivity to pertuzumab, or trastuzumab, or hyaluronidase, or to any of its excipients.

Additional Important Safety Information

Cardiomyopathy and Cardiac Monitoring

- PHESGO administration can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving PHESGO with anthracycline-containing chemotherapy regimens
- Discontinue PHESGO treatment in patients receiving adjuvant therapy and withhold PHESGO in patients with metastatic disease for clinically significant decrease in left ventricular function
- Evaluate cardiac function prior to and during treatment. For adjuvant therapy, also evaluate cardiac function after completion of PHESGO
- Monitor frequently for decreased left ventricular function during and after PHESGO treatment. Monitor more frequently if PHESGO is withheld for significant left ventricular cardiac dysfunction

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Important Safety Information (cont'd)

Additional Important Safety Information (cont'd)

Embryo-Fetal Toxicity

- PHESGO can cause fetal harm when administered to a pregnant woman
- Verify the pregnancy status of females of reproductive potential prior to the initiation of PHESGO. Advise pregnant women and females of reproductive potential that exposure to PHESGO during pregnancy or within 7 months prior to conception can result in fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 7 months following the last dose of PHESGO
- There is a pregnancy pharmacovigilance program for PHESGO. If PHESGO is administered during pregnancy, or if a patient becomes pregnant while receiving PHESGO or within 7 months following the last dose of PHESGO, health care providers and patients should immediately report PHESGO exposure to Genentech at 1-888-835-2555

Pulmonary Toxicity

- PHESGO can cause serious and fatal pulmonary toxicity. These adverse reactions have been reported with intravenous trastuzumab
- Pulmonary toxicity includes dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, non-cardiogenic pulmonary edema, pulmonary insufficiency and hypoxia, acute respiratory distress syndrome, and pulmonary fibrosis. Patients with symptomatic intrinsic lung disease or with extensive tumor involvement of the lungs, resulting in dyspnea at rest, appear to have more severe toxicity

Exacerbation of Chemotherapy-Induced Neutropenia

- PHESGO may exacerbate chemotherapy-induced neutropenia. In randomized controlled clinical trials with intravenous trastuzumab, Grade 3-4 neutropenia and febrile neutropenia were higher in patients receiving trastuzumab in combination with myelosuppressive chemotherapy as compared to those who received chemotherapy alone

Hypersensitivity and Administration-Related Reactions

- Severe administration-related reactions (ARRs), including hypersensitivity, anaphylaxis, and events with fatal outcomes, have been associated with intravenous pertuzumab and trastuzumab. Patients experiencing dyspnea at rest due to complications of advanced malignancy and comorbidities may be at increased risk of a severe or of a fatal ARR
- In the FeDeriCa study, the incidence of hypersensitivity was 1.2% in the PHESGO arm. ARRs occurred in 21% of patients who received PHESGO. In the PHESGO arm, the most common administration-related reactions were injection site reaction (15%) and injection site pain (2%)
- Closely monitor patients during and for 30 minutes after the injection of initial dose and during and for 15 minutes following subsequent injections of maintenance dose of PHESGO. If a significant injection-related reaction occurs, slow down or pause the injection and administer appropriate medical therapies. Evaluate and carefully monitor patients until complete resolution of signs and symptoms
- Permanently discontinue treatment with PHESGO in patients who experience anaphylaxis or severe injection-related reactions. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use. For patients experiencing reversible Grade 1 or 2 hypersensitivity reactions, consider pre-medication with an analgesic, antipyretic, or an antihistamine prior to readministration of PHESGO

Most Common Adverse Reactions

Early Breast Cancer

The most common adverse reactions (>30%) with PHESGO were alopecia, nausea, diarrhea, anemia, and asthenia.

Metastatic Breast Cancer (based on IV pertuzumab)

The most common adverse reactions (>30%) with pertuzumab in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy.

You are encouraged to report side effects to Genentech and the FDA. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

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Actor portrayal.

Consider starting or switching your eligible patients with HER2+ EBC or MBC to PHESGO today.

>90% of commercially insured patients have favorable access to PHESGO*[5]

New and existing PHESGO patients have favorable coverage to PI on most commercial plans, without pertuzumab + biosimilar trastuzumab IV regimen required first.

*Percentages of commercially insured patients with favorable access to PHESGO is defined as coverage at parity or better compared with pertuzumab + biosimilar trastuzumab IV regimens. Calculation is based on data updated as of November 2023. Less than 1% of patients do not have favorable coverage for PHESGO.

Learn how you could help your patients spend less time in the clinic.[1,2]

Visit PHESGO-HCP.com

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References: 1. PHESGO Prescribing Information. Genentech, Inc. 2020. **2.** PERJETA Prescribing Information. Genentech, Inc. 2021. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.5.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed December 19, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding the content, use or application of these guidelines and disclaims any responsibility for their application or use in any way. **4.** Waks A, et al. Patient time burden with IV vs SC administration of trastuzumab/pertuzumab (HP): a Time and Motion substudy of a single arm phase II trial of adjuvant endocrine therapy plus, HP for stage I HER2+ breast cancer. Poster presented at: San Antonio Breast Cancer Symposium, December 5-9, 2023; San Antonio, TX. **5.** Data on file. Genentech, Inc.

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