FDA Approves Breast Cancer Treatment That Can Be Administered at Home

New injectable combination can be administered by health care providers outside medical centers.

June 30, 2020 By Food and Drug Administration (FDA)

Today, the U.S. Food and Drug Administration approved Phesgo—a combination of pertuzumab, trastuzumab and hyaluronidase–zzxf—for injection under the skin to treat adult patients with HER2-positive breast cancer that has spread to other parts of the body, and for treatment of adult patients with early HER2-positive breast cancer. Patients should be selected based on an FDA-approved companion diagnostic test.

HER2-positive breast cancer, which makes up approximately one-fifth of breast cancers, has too much of a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells. Pertuzumab and trastuzumab bind to sites on HER2 and disrupt signaling to stop cancer cell growth. Phesgo is initially used in combination with chemotherapy and could continue to be administered at home by a qualified health care professional once the chemotherapy regimen is finished.

“Currently, most patients with HER2-positive breast cancer receive trastuzumab and pertuzumab at infusion centers. With a new administration route, Phesgo offers an out-patient option for patients to receive trastuzumab and pertuzumab,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. “As part of the FDA’s ongoing commitment to address the novel coronavirus pandemic, we continue to keep a strong focus on patients with cancer who constitute a vulnerable population at risk of contracting the disease. At this critical time, we continue to expedite oncology product development. This application was approved about four months ahead of the FDA goal date.”

Phesgo contains a fixed-dose combination of pertuzumab and trastuzumab with hyaluronidase for injection under the skin. The therapeutic components in Phesgo are the same as those in FDA-approved intravenous (IV) pertuzumab and IV trastuzumab.

The FDA’s approval was based on the results of a non-inferiority study in patients with HER2-

positive early breast cancer, which demonstrated Phesgo had comparable efficacy and safety as IV pertuzumab and IV trastuzumab, except for administration-related reactions, which were higher with Phesgo due to the subcutaneous route of administration.

Prescribing information for Phesgo includes a boxed warning to advise health care professionals and patients about the risk of potential heart failure, fetal harm and lung toxicity. Health care professionals should use similar monitoring parameters as those used with IV pertuzumab and IV trastuzumab.

The most common side effects for patients taking Phesgo were alopecia (hair loss), nausea, diarrhea, anemia (reduced number of red blood cells) and asthenia (lack of energy). Phesgo can cause worsening of chemotherapy induced neutropenia (low level of white blood cells).

Women who are pregnant should be advised that Phesgo may cause harm to a developing fetus or a newborn baby. The FDA advises health care professionals to inform females of reproductive age that exposure to Phesgo during pregnancy or within 7 months prior to conception can result in fetal harm.

Patients who experience anaphylaxis (severe allergic reaction) or severe hypersensitivity should discontinue Phesgo.

The FDA granted approval of Phesgo to Genentech Inc.

Click here for full prescribing information for Phesgo.

This announcement was originally published on the Food and Drug Administration website on June 29, 2020.
