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# FDA approves Roche’s Phesgo for HER2-positive breast cancer

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**Phesgo offers faster administration of Perjeta and Herceptin under the skin in just minutes, compared to hours with standard intravenous administration**

US Food and Drug Administration (FDA) has approved Roche's Phesgo™, a fixed-dose combination of Perjeta® (pertuzumab) and Herceptin® (trastuzumab) with hyaluronidase, administered by subcutaneous (SC; under the skin) injection in combination with intravenous (IV) chemotherapy, for the treatment of early and metastatic HER2-positive breast cancer. This is the first time that Roche has combined two monoclonal antibodies that can be administered by a single SC injection.

“The FDA approval of Phesgo reflects our commitment to improving outcomes for the many people living with HER2-positive breast cancer,” said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. “Phesgo offers a treatment administration that 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 is available in one single-dose vial. Administration can take approximately eight minutes for the initial loading dose and approximately five minutes for each subsequent maintenance dose. This is compared to approximately 150 minutes for a sequential infusion of a loading dose of Perjeta and Herceptin using the standard IV formulations, and between 60-150 minutes for subsequent maintenance infusions of the two medicines. Phesgo can be administered by a healthcare professional in a treatment centre or at a patient’s home.

The approval is based on results from the pivotal phase III FeDeriCa study, which met its primary endpoint with Phesgo showing non-inferior levels of Perjeta in the blood during a given dosing interval (Ctrough), when compared to IV administration of Perjeta. The safety profile of Phesgo with chemotherapy was comparable to IV administration of Perjeta plus Herceptin and chemotherapy, and no new safety signals were identified, including no meaningful difference in cardiac toxicity. The most common adverse events in both arms were alopecia, nausea, diarrhoea and anaemia.

The phase II PHranceSCa study showed that 85% (136/160) of people receiving treatment for HER2-positive breast cancer preferred treatment under the skin to IV administration due to less time in the clinic and more comfortable treatment administration.