Media & Investor Release

CHMP recommends EU label update for Roche's Phesgo to allow administration outside of clinical settings

- **Positive recommendation based on clinical, real-world and bioequivalence data supporting feasibility and safety of Phesgo's administration outside of clinical settings, for example at home[1-4]**
- **Phesgo label expansion delivers on patients' preference for at-home administration and is an important step in freeing up cancer care capacity in clinical settings[3]**
- **Phesgo has the potential to reduce treatment administration costs by up to 80% in Western Europe, and 85% of patients prefer SC over IV administration.[7,3]**

Basel, 30 April 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending an update to the European Union (EU) label for Phesgo®, a subcutaneous (SC) fixed-dose combination of Perjeta® (pertuzumab) and Herceptin® (trastuzumab), for human epidermal growth factor receptor 2 (HER2)-positive breast cancer. If approved, administration of Phesgo outside of a clinical setting (such as in a person's home) by a healthcare professional will be possible, once safely established in a clinical setting. A final decision regarding the approval is expected from the European Commission in the near future.

Each year, almost half a million people are diagnosed with HER2-positive breast cancer worldwide and treatment can impact a person's ability to work and contribute to society.[5,6]

"Between 2017 and 2023, the socioeconomic burden of HER2-positive breast cancer in ten major economies was nearly $590 billion, projected to increase to nearly $1,000 billion by 2032," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "At-home treatment may help alleviate the pressure on healthcare systems through significant capacity savings. This aligns with patient preferences, as data indicate 91% favour at-home administration over in-clinic treatment."

"Treatments, like Phesgo, that can be administered at home offer patients a more manageable option, with the potential to improve their quality of life," said Sandrine Lavallé from European Patients Academy on Therapeutic Innovation (EUPATI), Luxembourg. "This reduces the burden of hospital commuting time, anxiety associated with being in a hospital infusion chair, and minimizes disruption to daily life. Patient safety is paramount, requiring clear instructions, education, and support for at-home treatment."

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The CHMP positive opinion is supported by results from clinical, real-world and bioequivalence data, drug safety reports and the United States expanded access study, AL42478, in people with early-stage and metastatic HER2-positive breast cancer, which demonstrated that at-home administration of Phesgo by a healthcare professional was feasible, preferred by patients, and with no new safety signals observed.[1-4]

Phesgo is already approved as a SC alternative to intravenous (IV) Perjeta and Herceptin for people with HER2-positive early-stage and metastatic breast cancer in more than 120 countries/regions. In Western Europe, switching from IV Perjeta and Herceptin to Phesgo has been shown to reduce treatment administration costs by up to 80% and studies indicate that 85% of individuals with breast cancer prefer SC over IV administration.[7,3]

About Phesgo® (pertuzumab, trastuzumab, and hyaluronidase subcutaneous (SC))

Phesgo is a fixed-dose combination of Perjeta® (pertuzumab) and Herceptin® (trastuzumab) with hyaluronidase, administered by SC (under the skin) injection in combination with intravenous (IV) chemotherapy, for the treatment of early-stage and metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer.

The standard IV formulation of Perjeta in combination with IV Herceptin and chemotherapy (the Perjeta-based regimen) is approved in more than 120 countries/regions for the treatment of both early-stage and metastatic HER2-positive breast cancer. In the neoadjuvant (before surgery) early-stage breast cancer setting, the Perjeta-based regimen has been shown to almost double the rate of pathological complete response compared to Herceptin and chemotherapy.[8] Additionally, the combination has been shown to significantly reduce the risk of recurrence of invasive disease or death in the adjuvant (after surgery) early-stage breast cancer setting.[9] In the metastatic setting, the combination has shown an unprecedented survival benefit in previously untreated (first-line) patients with HER2-positive metastatic breast cancer.[10] Phesgo offers faster administration of Perjeta and Herceptin under the skin in approximately eight minutes, compared to hours with standard IV administration.[11-13]

About Roche's medicines for human epidermal growth factor receptor 2 (HER2)-positive breast cancer

Roche has been leading research into the HER2 pathway for over 30 years and is committed to improving the health, quality of life and survival of people with both early-stage and advanced HER2-positive disease. HER2-positive breast cancer affects approximately 15-20% of people with breast cancer.[6]

Survival outcomes for people with HER2-positive breast cancer, once was seen as an aggressive type of the disease, have been transformed through the development of targeted therapies, including Roche molecules Herceptin® (trastuzumab), Perjeta® (pertuzumab), Kadcyla® (trastuzumab emtansine) and Phesgo® (pertuzumab, trastuzumab, and hyaluronidase

subcutaneous). Long-term survival is now a possibility for many people, which also contributes to societal and economic benefits. Between 2017 to 2023, Roche's HER2-positive breast cancer medicines contributed a cumulative $8.2 billion to economic growth across ten major economies.[5]

Eligibility for treatment with Roche's HER2-targeted medicines is determined via a diagnostic test, which identifies people who will likely benefit from these medicines at the onset of their disease.

About Roche in breast cancer

Our medicines, along with companion diagnostic tests, have contributed to bringing breakthrough outcomes in human epidermal growth factor 2-positive and triple-negative breast cancers. As our understanding of breast cancer biology rapidly improves, we are working to identify new biomarkers and approaches to treatment for other subtypes of the disease, including oestrogen receptor-positive breast cancer, which is a form of hormone receptor-positive breast cancer, the most prevalent type of all breast cancers.[14,15]

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

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