Media Release

Roche receives FDA approval for the first companion diagnostic to identify patients with HER2-ultralow metastatic breast cancer eligible for ENHERTU

- **As seen in the DESTINY-Breast06 trial, approximately 20-25 percent of hormone receptor (HR)-positive, HER2-negative breast cancer patients may be considered HER2-ultralow.1 These patients may now be eligible for a targeted treatment, which could significantly improve their outcomes.**
- **The PATHWAY HER2 (4B5) test, the first and only FDA approved companion diagnostic for assessing HER2-low status since 2022, is now also approved to aid in the assessment of HER2-ultralow status for metastatic breast cancer patients.**
- **HER2 interpretation in breast cancer is evolving. With the introduction of HER2-low and now HER2-ultralow classifications, Roche continues to lead in HER2 diagnostics, helping to expand patient access to personalised treatment.**

Basel, 31 January 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved a label expansion for the PATHWAY® anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody* to identify patients with HR-positive, HER2-ultralow metastatic breast cancer who may be eligible for treatment with ENHERTU®. ENHERTU is a specifically engineered HER2-directed antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialised by Daiichi Sankyo and AstraZeneca.

Until the introduction of HER2-low status in 2022, HER2 status was categorised as either “positive” or “negative” based on the level of HER2 expression. The PATHWAY HER2 (4B5) test has now received approval to identify a new patient population designated as "HER2-ultralow." HER2-ultralow refers to patients who have very low levels of HER2 expression, even lower than the existing HER2-low category.

“One in eight women in the United States will face invasive breast cancer in their lifetime,” said Matt Sause, CEO of Roche Diagnostics. “The rising incidence of metastatic breast cancer, particularly among younger populations, underscores the urgent need for new diagnostic options. The approval of our test for determining HER2-ultralow status offers new hope to patients by providing a possible path to HER2-targeted treatment where none existed before, helping clinicians transform outcomes for many facing this challenging disease.”

HER2 is a receptor protein that helps cancer cells grow quickly. To determine a patient’s HER2 status, pathologists evaluate, or score, the level of HER2 receptor protein expressed in breast cancer tissue samples. The PATHWAY HER2 (4B5) test was used as part of the DESTINY-Breast06

trial, which showed a median progression-free survival of 13.2 months with ENHERTU compared to 8.1 months with the standard of care (chemotherapy) in the overall trial population of patients with HER2-low and HER2-ultralow metastatic breast cancer. An exploratory analysis showed the results were consistent between patients with HER2-low and HER2-ultralow expression.[2]

The FDA approval of the new HER2-ultralow indication expands on the intended use for Roche's on-market PATHWAY anti-HER2 (4B5) test, proven in delivering timely, clear, and confident results. The launch further strengthens and differentiates Roche's comprehensive breast cancer solutions portfolio, aiding patients and providers in making informed decisions to improve outcomes.

About PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Antibody

Roche's pre-diluted PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody, used in combination with the fully automated BenchMark IHC/ISH slide staining instrument, standardises all immunohistochemistry (IHC) processes from baking through staining and reduces the possibility of human error.[3] It also minimises inherent variability resulting from individual reagent dilution and other processes found in manual and semi-automated IHC methods. The Roche HER2 (4B5) clone achieves consistently high proficiency assessment scores compared to other clones [4] and demonstrates high concordance with HER2 FISH,[5,6] empowering laboratories to employ the most widely adopted and reliable HER2-IHC primary antibody.

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.

For more information, please visit www.roche.com.

* Hereafter referred to as PATHWAY HER2 (4B5) test

References

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[2] Bardia A, et. al. Trastuzumab Deruxtecan after Endocrine Therapy in Metastatic Breast Cancer, New England Journal of Medicine. 2024; 391:2110-2122
[3] PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody Package Insert
[4] NORDIQC HER2 IHC Assessment Run B37 2024
[5] Mayr D, et al. Comprehensive immunohistochemical analysis of Her-2/neu oncoprotein overexpression in breast cancer: HercepTest™ (Dako) for manual testing and Her-2/neuTest 4B5 (VENTANA) for VENTANA BenchMark automatic staining system with correlation to results of BenchMark automatic staining system with correlation to results of fluorescence in situ hybridization (FISH). Virchows Archiv. 2009; 454(3):241–248.
[6] Brügmann A, Lelkaitis G, Nielsen S, et al. Testing HER2 in breast cancer: a comparative study on BRISH, FISH, and IHC. Appl Immunohistochem Mol Morphol. 2011;19(3):203-211.

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