Media Release

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

- **Approximately half of all patients with metastatic breast cancer (mBC) express low levels of HER2. These patients with HER2 low status may now be eligible for a targeted treatment, which could significantly improve their outcomes.[1,2]**
- **The PATHWAY anti-HER2 (4B5) test is the only FDA approved companion diagnostic indicated as an aid in the assessment of HER2 low status in metastatic breast cancer patients. These patients may now consider ENHERTU as a treatment option based on the results of the Phase 3 DESTINY-Breast04 trial.[3]**

Basel, 4 October 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) approved the PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody* to identify metastatic breast cancer patients with low HER2 expression for whom ENHERTU® (fam-trastuzumab deruxtecan-nxki) may be considered as a targeted treatment. ENHERTU is a specifically engineered HER2-directed antibody drug conjugate (ADC) being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

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. If a patient's tumour expresses high levels of HER2, the patient is identified as HER2-positive and may be considered for HER2-targeted treatment. However, half of all patients with metastatic breast cancer express low levels of HER2 which historically classified them as HER2-negative.

The PATHWAY anti-HER2 (4B5) test now includes a scoring algorithm that helps pathologists to identify "low expressors" of HER2, assigning a HER2 low status to this group of patients. With this lower cutoff, the test is able to identify patients who may benefit from ENHERTU as a treatment option.

"Roche is proud to lead the way in HER2 diagnostics through critical innovations that support the identification of patients who may benefit from novel HER2-targeted therapies," said Thomas Schinecker, CEO of Roche Diagnostics. "Previously, metastatic breast cancer patients with a lower level of HER2 expression were considered to be part of the HER2-negative population and had no HER2-targeted treatment options. Now, they may be eligible for a HER2-targeted therapy, significantly increasing the number of patients who could have improved outcomes."

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The PATHWAY anti-HER2 (4B5) test was used as part of the DESTINY-Breast04 trial sponsored by AstraZeneca and Daiichi Sankyo to identify patients whose tumours expressed low levels of HER2 protein. The trial reported a 50% reduction in the risk of disease recurrence or death and an overall gain of six months over standard of care in patients treated with ENHERTU whose tumours had low levels of HER2 expression.

Breast cancer has surpassed lung cancer as the most commonly diagnosed cancer, with an estimated 2.3 million new cases diagnosed worldwide each year. More than 620,000 people die from breast cancer every year.[4,5]

The FDA approval of the new HER2 low indication expands on the intended use for Roche's proven, on-market PATHWAY anti-HER2 (4B5) test, delivering timely, clear and confident results. The launch exemplifies Roche's commitment to continuing to innovate integrated, high medical value solutions that help to advance personalised healthcare.

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.[5] 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[6] and demonstrates high concordance with HER2 FISH[7,8], empowering laboratories to employ the most widely adopted and reliable HER2-IHC primary antibody.

About Roche

Founded in1896 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.

In recognizing our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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 anti-HER2 (4B5) test

References

[1] AstraZeneca news release
[2] Daiichi Sankyo news release
[3] ASCO publication
[4] Sung, Hyuna, et al. Global Cancer Statistics 2020
[5] PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody Package Insert
[6] NordiQC Assessments
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[8] 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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