Media Release

FDA approves Roche's new VENTANA HER2 Dual ISH test as companion diagnostic to identify breast cancer patients eligible for targeted therapy

- Nearly 2.1 million new cases of breast cancer are diagnosed worldwide each year, and more than 620,000 people will die from the disease.[1] About 15 to 20 percent of women diagnosed with breast cancer are HER2 positive.[2]
- VENTANA HER2 Dual ISH DNA Probe Cocktail assay[3] aids in identifying HER2-positive breast cancer patients eligible for the targeted Roche drug Herceptin (trastuzumab)
- Developed with enhanced technology, this new assay provides high-quality staining with improved turnaround time

Basel, XX July 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced US Food and Drug Administration (FDA) approval of the new VENTANA HER2 Dual ISH DNA Probe Cocktail assay for the detection of the HER2 biomarker in breast cancer and as a companion diagnostic for Herceptin (trastuzumab) therapy. HER2 - human epidermal growth factor receptor 2 - is an important biomarker sometimes found in breast cancers.[2] Its detection and inhibition can help healthcare professionals more effectively manage this aggressive cancer.

The VENTANA HER2 Dual ISH DNA Probe Cocktail assay is designed to be completed within the same day, enabling clinicians to get results back faster than with other common methods of confirmatory testing for HER2. Results can be read using light microscopy, eliminating the need for a specialised fluorescence microscope.

"With this new VENTANA HER2 Dual ISH assay, Roche continues to deliver on its commitment to advance personalised healthcare," said Thomas Schinecker, CEO Roche Diagnostics. "Quick results are crucial in the fight against cancer and by delivering critical information on treatment options for breast cancer patients faster, this assay will aid clinicians in their therapeutic decisions."

This assay was launched as a CE IVD in April 2019.

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The new VENTANA HER2 Dual ISH DNA Probe Cocktail assay is one component of Roche's comprehensive breast cancer solutions portfolio designed to help inform decision-making in cancer care and contribute to improved patient outcomes. For more information about the assay and the portfolio, please visit the Roche Tissue Diagnostics breast cancer IHC/ISH portfolio page or the Anatomic Pathology site.

About the VENTANA HER2 Dual ISH DNA Probe Cocktail assay
Roche is the only provider of an FDA approved ready-to-use brightfield Dual ISH solution for the detection of HER2 amplification. The new VENTANA HER2 Dual ISH DNA Probe Cocktail assay is optimized for use with the VENTANA Silver ISH DNP Detection Kit and the VENTANA Red ISH DIG Detection Kit on the fully-automated BenchMark ULTRA.

The VENTANA HER2 Dual ISH DNA Probe Cocktail assay is an enhanced version of the previous-generation test. New oligonucleotide probes and highly sensitive detection kits provide clear results to pathology labs more quickly, allowing clinicians to make treatment decisions earlier.

As a global leader in breast cancer diagnostics, Roche provides a comprehensive menu of both diagnostic and predictive assays, including the PATHWAY HER2/neu (4B5) Rabbit Monoclonal Primary Antibody that is indicated as an aid in the assessment of breast cancer patients for whom Herceptin treatment is considered.

About Herceptin (trastuzumab)
Herceptin® is a humanised monoclonal antibody designed to target and block the function of the HER2 receptor, a protein found on the outside of many normal cells and in high quantities on the outside of cancer cells in HER2-positive cancers. Herceptin binds to a specific section of the HER2 protein, inhibiting the signals it sends that encourage tumour cell growth, while also calling on the body's immune system to attack the cancer cells.

Since it was first approved in 1998, Herceptin has been used to treat over two million patients worldwide, diagnosed with HER2-positive breast and gastric cancers. It has also become the backbone of other innovative treatments for HER2-positive breast cancer, which have continued to improve the outcomes of patients with this otherwise aggressive disease. In addition to the standard intravenous formulation, Herceptin is available in a subcutaneous (SC) formulation which was first approved in 2013. Herceptin SC represents a significant

step forward in the treatment of HER2-positive breast cancer as it offers patients a faster, more convenient and less painful way to receive treatment with Herceptin.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.

References

[1] World Health Organization. GLOBOCAN 2018; All cancers fact sheet. [Interned; cited July 2020]. Available from: https://gco.iarc.fr/today/data/factsheets/cancers/39-All-cancers-fact-sheet.pdf
[2] Wolff AC, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline update. J Clin Oncol. 2013;31(31):3997-4013.
[3] This product is intended for in vitro diagnostic (IVD) use.

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