Roche launches new VENTANA HER2 Dual ISH companion diagnostic test for breast and gastric 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

- The VENTANA HER2 Dual ISH DNA Probe Cocktail assay³ aids in identifying breast and gastric cancer patients eligible for the targeted Roche drug Herceptin (trastuzumab), providing fast results with widely available laboratory instruments.

- This approval supports Roche's personalized healthcare strategy to provide treatment to patients who can benefit most from a specific medicine.

Basel, 23 April 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of the new VENTANA HER2 Dual ISH DNA Probe Cocktail assay for the detection of the HER2 biomarker in breast and gastric cancer. HER2 - human epidermal growth factor receptor 2 - is an important biomarker found in breast and gastric cancers.⁴ Its detection and inhibition can help to more effectively manage these aggressive cancers.

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

“The new VENTANA HER2 Dual ISH assay advances Roche's commitment to personalized healthcare by delivering critical information on treatment options for breast and gastric cancer patients faster,” said Michael Heuer, CEO Roche Diagnostics. “Quick results are crucial in the fight against cancer, and every additional day that a clinician and a patient must wait for test results is a day too long.”

This assay is currently being launched in Europe, the Middle East and Africa, as well as Latin America and Asia Pacific. It will be submitted to the U.S. Food and Drug Administration for approval.

For more information about the assay, 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 a fully automated brightfield Dual ISH solution for the detection of HER2 amplification. With the new VENTANA HER2 Dual ISH DNA Probe Cocktail assay, Roche provides an improved brightfield assay that is fully automated on the BenchMark IHC/ISH instruments. The assay provides 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 VENTANA 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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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.

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References

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow