Roche launches two digital pathology image analysis algorithms for precision patient diagnosis in breast cancer

- **uPath HER2 (4B5) image analysis and uPath Dual ISH image analysis aid pathologists in providing faster, more accurate patient diagnoses in breast cancer**
- **In combination with the VENTANA DP 200 slide scanner and Roche uPath enterprise software, the new algorithms provide innovative digital pathology solutions to advance personalised healthcare**
- **Nearly 2.1 million new cases of breast cancer are diagnosed worldwide each year. About 15 to 20 percent of women diagnosed with breast cancer are HER2 positive**

Basel, 11 January 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the CE-IVD launch of its automated digital pathology algorithms, uPath HER2 (4B5) image analysis and uPath Dual ISH image analysis for breast cancer to help determine the best treatment strategy for each patient. The image analysis algorithms use artificial intelligence to support pathologists in making faster, more accurate patient diagnoses in breast cancer.

A mutation in the HER2 gene, which occurs in as many as 20 percent of the 2.1 million cases of breast cancer diagnosed globally each year, is responsible for aggressive growth in some patients. Identifying this mutation is important in determining which patients may benefit from targeted treatment.[1,2]

“About 15 to 20 percent of women diagnosed with breast cancer are HER2 positive, which makes fast and accurate diagnosis critical,” said Thomas Schinecker, CEO Roche Diagnostics. “Roche is continuing to innovate in HER2 diagnostics by providing precise information through image analysis algorithms for pathology decision support.”

uPath HER2 (4B5) image analysis for breast cancer helps pathologists to quickly determine whether tumors are positive for the HER2 biomarker, highlighting positively stained tumor cell membranes with a clear visual overlay for easy reference. uPath HER2 Dual ISH image analysis for breast cancer assists the pathologist in the determination of HER2 gene amplification. A heatmap is provided to guide pathologists to areas of interest where the algorithm can identify cells to inform the determination of a treatment strategy.

Validated on the VENTANA HER2 (4B5) assay and the VENTANA HER2 Dual ISH DNA Probe Cocktail, the algorithms are ready-to-use and integrated within the Roche uPath enterprise software. The uPath HER2 (4B5) image analysis and uPath HER2 Dual ISH image analysis algorithms for breast cancer expand Roche’s digital pathology portfolio to empower precision diagnosis. Roche is continuing to innovate in HER2 diagnostics through image analysis algorithms that provide an actionable assessment of scanned slide images that are objective and reproducible.

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland | Group Communications Roche Group Media Relations | Tel. +41 61 688 88 88 www.roche.com

About uPath image analysis algorithm suite
The uPath image analysis algorithm suite for pathology decision support offers ready-to-use image analysis tools, providing fast, consistent and automated analysis so that pathologists can quickly, accurately and confidently assess immunohistochemistry and in situ hybridization. All algorithms in the suite for uPath software will provide image analysis of VENTANA DP 200 scanned slide images stained with a Roche Tissue Diagnostics assay. Together, Roche is delivering a new foundation of its digital pathology solution which will enable the development of artificial intelligence-based image analysis algorithms that can provide pathologists more tools to improve efficiency and precision.

Roche is delivering the end-to-end digital pathology solution from tissue staining to producing high-quality digital images that can be reliably assessed using automated clinical image analysis algorithms. Roche minimizes the variables that can impact analysis, and it is this end-to-end development that produces the quality results customers can depend on for making clinical decisions. With the acceleration of immunotherapy and the development of more complex assays, Roche is moving these traditionally research-oriented tools into routine clinical practice.

About breast cancer
Breast cancer is the second most common cancer in the world, with an estimated 1.7 million new cancer cases diagnosed in 2012 (25% of all cancers). It is the most common cancer in women globally. Incidence rates vary nearly four-fold across the world regions, with rates ranging from 27 per 100,000 in Africa and Asia to 92 per 100,000 in North America.[1,2]

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 twelfth 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.

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Dr. Daniel Grotzky
Phone: +41 61 688 31 10

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com