Media & Investor Release

Roche granted FDA Breakthrough Device Designation for first AI-driven companion diagnostic for non-small cell lung cancer

- **The VENTANA TROP2 (EPR20043) RxDx Device is an immunohistochemistry (IHC) assay combined with a digital pathology algorithm to determine patient treatment.**
- **The device uses artificial intelligence-based image analysis with a level of diagnostic precision not possible with traditional manual scoring methods.**
- **This Breakthrough Device Designation (BDD) demonstrates Roche's continued innovation in companion diagnostics and digital pathology to enable more precise diagnosis in oncology.**

Basel, 29 April 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation for the VENTANA® TROP2 (EPR20043) RxDx Device. This is the first Breakthrough Device Designation to be granted for a computational pathology companion diagnostic (CDx) device.

"This FDA Breakthrough Device Designation is another example of our commitment to deliver innovation that enables more precise diagnosis in oncology," said Matt Sause, CEO of Roche Diagnostics. "This solution, which leverages our industry-leading expertise in companion diagnostics development, uses artificial intelligence for a greater depth of sample analysis, helping to deliver truly personalised treatment."

The VENTANA TROP2 (EPR20043) RxDx Device is a computational pathology device, consisting of the TROP2 algorithm, navify® Digital Pathology Image Management System, Roche Digital Pathology scanners (DP 200, DP 600) and the VENTANA TROP2 (EPR20043) RxDx Assay used with OptiView DAB Detection Kit for staining on a BenchMark ULTRA IHC/ISH staining instrument. The VENTANA TROP2 (EPR20043) RxDx Device analyses whole slide images of non-small cell lung cancer (NSCLC) tissue stained with TROP2 to compute a quantitative TROP2 score.

The algorithm incorporates AstraZeneca's proprietary computational pathology platform, Quantitative Continuous Scoring (QCS), which enables a level of diagnostic precision not possible with traditional manual scoring methods.

"This FDA Breakthrough Device Designation underscores the potential of our computational pathology platform to enable more personalised treatment decisions for people with cancer," said Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca.

The FDA granting Breakthrough Device Designation has the potential to make a TROP2 CDx AI-driven system available sooner, which could aid in identifying patients with NSCLC most

likely to benefit from treatment with Daiichi Sankyo and AstraZeneca's DATROWAY® (datopotamab deruxtecan-dlnk). DATROWAY is a specifically engineered TROP2-directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed by AstraZeneca and Daiichi Sankyo.

About the VENTANA TROP2 (EPR20043) RxDx Device

The VENTANA TROP2 (EPR20043) RxDx Device is indicated as an aid in identifying patients with previously treated advanced or metastatic non-squamous NSCLC without actionable genomic alteration (AGA) most likely to benefit from treatment with Daiichi Sanko and AstraZeneca's DATROWAY (datopotamab deruxtecan-dlnk). A qualified pathologist is responsible for reviewing staining and image quality, as well as ensuring adequate tumor detection sensitivity and precision, in conjunction with histological examination, relevant clinical information, and proper controls.

Following the pathologist assessment, the nDP TROP2 algorithm independently detects tumor cells and generates associated measures of TROP2 IHC staining intensity in both membrane and cytoplasm to compute the Normalised Membrane Ratio (NMR) score. The algorithm then classifies the TROP2 status as positive or negative based upon the pre-defined NMR cutoff.

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.

Roche Global Media Relations

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

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Simon Goldsborough
Phone: +44 797 32 72 915

Nina Mählitz
Phone: +41 79 327 54 74

Yvette Petillon
Phone: +41 79 961 92 50

Sileia Urech
Phone: +41 79 935 81 48

Lorena Corfas
Phone: +41 79 568 24 95

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +49 172 6367262

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Roche Investor Relations

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

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

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

Investor Relations North America

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