Media Release

Roche obtains CE certification for the first companion diagnostic to identify patients with gastric and gastroesophageal junction cancer eligible for targeted treatment with VYLOY

- **The new VENTANA CLDN18 (43-14A) RxDx Assay helps fulfil an unmet medical need by enabling clinicians to identify patients with gastric or gastroesophageal junction (GEJ) cancer who may benefit from a targeted treatment option.**
- **CLDN18.2 is an emerging biomarker in gastric and GEJ cancers and helps predict the likelihood of response to targeted therapy.**
- **As the leader in companion diagnostics, Roche continues to build on its commitment to improve personalised healthcare to enable better patient outcomes.**

Basel, 10 October 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the VENTANA® CLDN18 (43-14A) RxDx Assay is the first immunohistochemistry (IHC) companion diagnostic test to receive CE Mark approval for determining CLDN18 protein expression in tumours of patients with gastric or gastroesophageal junction (GEJ) adenocarcinoma. These patients now may be eligible for treatment with Astellas' targeted therapy VYLOY™ (zolbetuximab).

"Gastric cancer remains a significant global health challenge. In Europe, only three percent of patients with metastatic disease live beyond five years," said Matt Sause, CEO of Roche Diagnostics. "Our new companion diagnostic is a significant step forward for patients. By identifying those who may benefit from a targeted treatment, this new test can expand treatment possibilities, and aid clinicians to potentially improve outcomes."

Current guidelines for gastric/GEJ cancer recommend using biomarkers to guide therapeutic decision making. The new VENTANA CLDN18 (43-14A) RxDx Assay can help determine CLDN18.2 status and inform clinicians about the likelihood of patients benefiting from CLDN18.2 targeted therapy.[4] VYLOY is the first approved treatment specifically targeting CLDN18.2-positive gastric/GEJ cancer, expanding options for patients to receive therapies appropriate for their specific disease.[5]

Gastric cancer is the fifth most common cancer worldwide,[1] with some of the highest rates observed in Central and Eastern Europe.[1] The disease is often diagnosed late, because signs and symptoms are common to other conditions,[6] resulting in an overall survival rate of just 25% among patients in the EU.[7]

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About the VENTANA CLDN18 (43-14A) RxDx Assay

The VENTANA CLDN18 (43-14A) RxDx Assay is a qualitative immunohistochemical assay intended to be used in the assessment of Claudin 18 (CLDN18) protein in gastric adenocarcinoma including gastroesophageal junction (GEJ) adenocarcinoma. The OptiView DAB IHC Detection Kit is used for staining on a BenchMark ULTRA instrument. The assay is indicated as an aid in identifying patients with gastric or GEJ adenocarcinoma who may be eligible for treatment with VYLOY® (zolbetuximab) in accordance with the approved therapeutic product labelling. The Roche test measures expression of both variants of the CLDN18 protein (18.1 and 18.2 isoforms). CLDN18.2 is the predominant variant expressed in gastric and GEJ cancers.[4,8]

The approval of the VENTANA CLDN18 (43-14A) RxDx Assay is based on the results of the SPOTLIGHT and GLOW clinical studies where it was used as the enrollment assay to identify patients whose tumours were CLDN18.2 positive. CLDN18.2 positivity is defined as ≥ 75% of tumour cells demonstrating moderate to strong membrane CLDN18 staining as measured by the VENTANA CLDN18 (43-14A) RxDx Assay. In these studies, approximately 38% of gastric/GEJ cancer patients expressed high levels of CLDN18 and were considered CLDN18.2 positive by the VENTANA CLDN18 (43-14A) RxDx Assay. Patients who received a combination of zolbetuximab and chemotherapy experienced a 25-31% reduction in disease progression or death.[9,10]

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.

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