Media Release

Roche receives FDA approval for the VENTANA MET (SP44) RxDx Assay as the first companion diagnostic to identify non-squamous non-small cell lung cancer patients eligible for treatment with Emrelis

- **The VENTANA MET (SP44) RxDx Assay detects the MET (also known as c-Met) protein, which is over-expressed in some patients with non-squamous non-small cell lung cancer (NSQ-NSCLC).**
- **The MET protein serves as a predictive biomarker for the likelihood of a patient's response to c-Met-targeted therapy.[1]**
- **As the leader in companion diagnostics, Roche's broad CDx portfolio helps enable informed clinical decisions and improved patient outcomes.**

Basel, 14 May 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the FDA has approved the VENTANA® MET (SP44) RxDx Assay, the first companion diagnostic approved to aid in determining MET (also known as c-Met) protein expression in NSQ-NSCLC patients. These patients may now be eligible for treatment with AbbVie's c-Met-targeted therapy Emrelis™ (telisotuzumab vedotin-tllv).[2,3]

"Understanding the molecular drivers in patients with non-small cell lung cancer is critical for therapy selection," said Matt Sause, CEO of Roche Diagnostics. "By identifying MET protein expression at the appropriate stage in the patient journey, we can help provide timely, tailored treatment options that may improve patient outcomes and offer hope to those facing this challenging disease."

Despite advances in treatment, lung cancer remains the leading cause of cancer-related deaths in both men and women throughout the world.[4] Lung cancer is often diagnosed at an advanced stage when treatment options are limited;[5] median survival is less than one year.[2] Approximately 85% of lung cancers are classified as NSCLC.[6]

Among advanced NSCLC patients with a normal (wild-type) epidermal growth factor receptor (EGFR) gene, around a quarter exhibit high levels of MET protein,[7] making MET protein expression an important factor in determining treatment options for patients with this type of cancer.

The FDA accelerated approval is supported by data from the Phase 2 LUMINOSITY study, an ongoing study designed to characterize the efficacy and safety of Emrelis in c-Met overexpressing advanced NSQ-NSCLC populations. Findings from the study showed patients with c-Met protein high expression who received Emrelis demonstrated 35% overall response rate (ORR) and duration of response (DoR) with a median of 7.2 months.[8]

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The launch of the first immunohistochemistry (IHC) MET companion test exemplifies Roche's commitment in this area, and represents an important addition to the company's market-leading portfolio of immunohistochemistry (IHC) and in situ hybridisation (ISH) companion diagnostics. These diagnostics are designed to provide critical insights that enable more informed clinical decisions, advancing personalised healthcare and improving patients' lives.

About the VENTANA MET (SP44) RxDx Assay

The VENTANA MET (SP44) RxDx Assay detects the MET protein and is scored by pathologists based on the percentage of tumour cells stained and the intensity of the staining.[2,3] The FDA's approval is based on data from AbbVie's Phase 2 LUMINOSITY clinical study, in which the test was used as the enrollment assay. MET protein overexpression is defined as ≥50% tumor cells demonstrating strong (3+) membrane and/or cytoplasmic staining.[9]

By providing critical information on MET protein expression, the assay informs clinicians about the likelihood that a patient will benefit from c-Met-targeted therapy, allowing for a more personalised approach to treating NSQ-NSCLC.

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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[9] AbbVie Announces Positive Topline Results from Phase 2 LUMINOSITY Trial Evaluating Telisotuzumab-Vedotin (Teliso-V) for Patients with Previously Treated Non-Small Cell Lung Cancer (NSCLC) November 2023

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