Media Release

Roche receives FDA approval for companion diagnostic tests to identify patients with HER2-positive, metastatic gastroesophageal adenocarcinoma eligible for ZIIHERA

- **The PATHWAY HER2 (4B5) test and VENTANA® HER2 Dual ISH DNA Probe Cocktail help identify HER2-positive, metastatic gastric, gastroesophageal junction and esophageal adenocarcinoma.**
- **Differential diagnosis of these cancers, often aggressive and diagnosed at an advanced stage, is critical to improving patient outcomes.**
- **Together, the tests enable precise assessment of HER2-positive status to help identify patients eligible for treatment with ZIIHERA.**

TUCSON, Ariz., August 26, 2026 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for expanded use of its PATHWAY® HER2 (4B5) and VENTANA® HER2 Dual ISH DNA Probe Cocktail tests. These companion diagnostics are now approved to assess HER2-positive status in metastatic gastroesophageal adenocarcinoma (GEA) patients, including those with gastric, gastroesophageal junction and esophageal adenocarcinoma. The approval enables clinicians to identify HER2-positive GEA patients who may be eligible for HER2-targeted treatment with Jazz Pharmaceuticals' ZIIHERA® (zanidatamab-hrii). Two ZIIHERA-containing regimens are now FDA approved for the first-line treatment of adults with unresectable locally advanced or metastatic HER2-positive GEA.

Gastroesophageal adenocarcinoma encompasses a group of related cancers originating in the gastrointestinal tract, including gastric and esophageal cancer. These closely related, aggressive cancers are typically diagnosed at a later stage[1,2] and are the fifth (gastric) and sixth (esophageal) leading causes of cancer deaths worldwide.[3] Despite advances in diagnosis and treatment, the prognosis for these cancers remains poor, with limited therapeutic options available.[4,5]

“GEA can be a difficult diagnosis for patients to face, with most cases only being detected once the disease has progressed to an advanced stage,” said Laura Apitz, Head of Pathology Lab at Roche Diagnostics. "By adding GEA to the approved indications for our widely-available HER2 assay, we expand the patient population eligible for targeted therapy and potentially improve patient outcomes."

This FDA approval broadens the population of patients eligible for HER2-targeted therapies to include those with HER2-positive GEA.[6] Until now, no tests had been approved to determine HER2 status in esophageal cancer, meaning patients were unable to access targeted therapy. Already widely used and trusted in breast and gastric cancers, these tests are an important step forward in providing access to new treatment options for this hard-to-treat disease.

About the PATHWAY HER2 (4B5) test and VENTANA HER2 Dual ISH DNA Probe Cocktail

The PATHWAY® HER2 (4B5) Rabbit Monoclonal Primary Antibody test and VENTANA® HER2 Dual ISH DNA Probe Cocktail work together to assess HER2 status, delivering diagnostic precision and enabling timely therapeutic decisions for patients with HER2-positive cancers. Together, these tests provide labs and pathologists with reliable, actionable insights to support personalized treatment approaches.

The PATHWAY® HER2 (4B5) test is the most widely adopted HER2-immunohistochemistry (IHC) primary antibody globally,[7] achieving consistently high proficiency-assessment scores[7] and demonstrating high concordance with HER2 FISH testing.[8,9] Its design ensures accuracy and reproducibility, with integration into the fully automated VENTANA BenchMark platform to minimize variability and reduce manual steps across all IHC processes.

The VENTANA® HER2 Dual ISH DNA Probe Cocktail enables the advanced detection of HER2 gene amplification. With its dual-color technology, pathologists can easily compare HER2 status with H&E and other GI panel markers within the same case,[10] helping to ensure consistent and confident diagnoses. The test also maintains high concordance with HER2 FISH testing,[11] making it a reliable component of HER2 diagnostic workflows.

Together, the tests strengthen Roche's comprehensive HER2 diagnostic portfolio. By delivering reliable and actionable results, they support diagnostic precision across multiple cancer types, expanding access to personalized treatment options, with the goal of improving outcomes for patients facing HER2-positive cancers.

For more information about the portfolio, please visit the Roche Diagnostics Pathology Lab companion diagnostics page.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland, in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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