Media Release

Roche receives FDA approval 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 fulfill 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 personalized healthcare to enable better patient outcomes.**

INDIANAPOLIS, October 18, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the VENTANA® Claudin 18 (43-14A) RxDx Assay is the first U.S. Food and Drug Administration (FDA) approved immunohistochemistry (IHC) companion diagnostic for determining CLDN18 protein expression in tumors of patients with gastric or gastroesophageal junction (GEJ) adenocarcinoma. These patients now may be eligible for treatment with Astellas' targeted therapy VYLOY® (zolbetuximab).

"Patients who are diagnosed with gastric or gastroesophageal junction cancer are often diagnosed in an advanced stage as early symptoms can be similar across several conditions," said Matt Sause, CEO of Roche Diagnostics. "Our companion diagnostic for CLDN18 can help identify patients eligible for targeted treatment and provide them with additional therapeutic options. With the launch of this test, Roche continues to advance personalized healthcare by expanding our innovative companion diagnostic portfolio."

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. VYLOY is the first FDA-approved treatment specifically targeting HER2-negative locally advanced unresectable or metastatic gastric or GEJ cancer patients whose tumors are CLDN18.2 positive.

Gastric cancer is the fifth most common cancer and the fourth leading cause of cancer deaths worldwide.[1] In the U.S., 62% of gastric/GEJ cancer cases are advanced when initially diagnosed, contributing to a five-year overall survival rate of only 6%.[2,3] Although gastric/GEJ cancer is less prevalent in the U.S. than in other parts of the world, it is often diagnosed late as signs and symptoms are common to other conditions.[4]

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) tissue. 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 labeling. 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.[5,6]

The approval of the VENTANA CLDN18 (43-14A) RxDx Assay is based on the results of the SPOTLIGHT and GLOW clinical studies, in which it was used as the enrollment assay to identify patients whose tumors were CLDN18.2 positive. CLDN18.2 positivity is defined as ≥ 75% of tumor 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% to 31% reduction in disease progression or death.[7,8]

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 personalized 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.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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

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