Media Release

Roche receives FDA clearance for new, highly sensitive test to aid clinicians in diagnosing B-cell lymphoma

- **The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail assay is the first clinically approved, in-situ hybridization (ISH) test with the sensitivity to assess the full spectrum of B-cell lymphoma subtypes.[1,2]**
- **The test helps differentiate a B-cell cancer from a normal, reactive immune response, offering diagnostic certainty for healthcare providers and their patients.**
- **B-cell lymphoma accounts for approximately 85% of non-Hodgkin lymphoma cases, which is one of the most common cancers in the U.S.[3]**

TUCSON and INDIANAPOLIS, January 13, 2025 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its highly sensitive, in-situ hybridization (ISH) test, the VENTANA® Kappa and Lambda Dual ISH mRNA Probe Cocktail.[4] The test is designed to help pathologists differentiate a B-cell malignancy from a normal, reactive response to an infection, thus facilitating faster access to treatment.[4] This announcement follows the assay's CE Mark approval in Europe in June 2024.

B-cell lymphoma is a type of cancer that typically develops in the lymphatic system. It accounts for approximately 85% of non-Hodgkin lymphoma (NHL) cases.[3] NHL is one of the most common forms of cancer in the U.S., accounting for about 4% of all cancer cases and causing more than 80,000 deaths each year.[5] In the early stages of NHL, patients may experience symptoms like swelling of the lymph nodes, fever, fatigue, loss of appetite or a red rash.

“Accurately differentiating lymphoma from an infection is critical in ensuring accurate and timely diagnosis, especially as the symptoms can appear similar,” said Jill German, Head of Pathology Lab at Roche Diagnostics. “With this new test, clinicians can have confidence in their diagnosis, while the test reduces the need for multiple samples and time-consuming follow-up tests, giving patients certainty sooner and enabling faster access to the right treatment.”

With increased sensitivity, the new VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail enables assessment across the more than 60 B-cell lymphoma subtypes and plasma cell neoplasms on a single tissue slide. The test can assess small biopsies and formalin-fixed tissue, reducing the need for a fresh tissue sample, which may not be available especially if lymphoma was not originally suspected. These test properties preserve tissue, may result in fewer additional patient biopsies and make interpretation quicker and easier for the pathologist, helping facilitate a faster diagnosis and access to treatment for patients.

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This first-of-its-kind assay is a significant addition to Roche's industry-leading hematopathology portfolio, which includes more than 65 biomarkers.

About the VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail

The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail Assay is a qualitative assay that is used to detect the expression of kappa and lambda immunoglobulin light chains in formalin-fixed paraffin embedded (FFPE) human hematolymphoid specimens by in situ hybridization (ISH).

The assay is intended as an aid in the diagnosis of mature B-cell lymphomas and plasma cell neoplasms. The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail is indicated for use when a biopsy of lymph node or bone marrow (core biopsy and clot section) indicates inconclusive results. It enables the assessment of both markers in the context of one another on a single slide as an aid in differentiating between a reactive process or B-cell lymphoma and plasma cell neoplasms.

This is not a standalone test, and results should be evaluated by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This product is intended for in-vitro diagnostic (IVD) use.[4]

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.

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.

References

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