Media Release

Roche granted FDA Breakthrough Device Designation for pTau217 blood test to support earlier Alzheimer's disease diagnosis

- **The Elecsys® pTau217 plasma biomarker test is being developed as part of an ongoing partnership between Roche and Eli Lilly and Company**
- **Once approved, the test will aid healthcare providers in identifying amyloid pathology, a key feature of Alzheimer's disease**
- **Roche and Lilly believe the test could play an important role in improving access to early and accurate Alzheimer's diagnosis**

BASEL, April 11, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its Elecsys pTau217 assay received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA). This blood test, which is being developed in collaboration with Eli Lilly and Company, will be used to help identify the presence or absence of amyloid pathology in individuals, which can help ensure they are able to receive appropriate care. This may include participation in clinical trials or access to approved disease-modifying therapies. If approved, the test could help rapidly broaden access to a more timely and accurate diagnosis and potentially mitigate the impact of Alzheimer's disease on people and society.

"The incidence of dementia is growing worldwide, with 75% of cases remaining undiagnosed.[1] Consequently, there is a critical role for Diagnostics to play in addressing this global health challenge," said Matt Sause, CEO of Roche Diagnostics. "We believe pTau217 is going to be crucial in the diagnosis of Alzheimer's disease, a condition for which Roche Diagnostics is committed to improving the lives of patients worldwide. We plan to leverage our installed base of diagnostic systems, which is the largest in the world, to ensure we are able to create access to this test for those who need it the most."

"The development of the Elecsys pTau217 plasma assay is another milestone in our collaboration with Roche Diagnostics that will advance the Alzheimer's diagnostic ecosystem," said Anne White, executive vice president of Eli Lilly and Company and president of Lilly Neuroscience. "We're excited to help meet the growing need for additional diagnostic tools to enable a timely and accurate diagnosis for people with Alzheimer's disease."

pTau217, which is a phosphorylated fragment of the protein tau, is a biomarker that has shown the ability in research settings to distinguish Alzheimer's disease from other neurodegenerative disorders and has shown strong performance relative to other biomarkers.[2]

As global leaders in Alzheimer's innovation, Roche and Lilly hope that this collaboration can bring additional speed and scale to testing and diagnosis in this important area of unmet medical need.

About Elecsys pTau217

Elecsys Phospho-Tau (217P) is intended to be an in-vitro diagnostic immunoassay for the quantitative determination of the protein Phospho-Tau (217P) (pTau217) in human plasma

from individuals aged 60 years and older. The test is intended for use as an aid in identifying amyloid pathology, a pathological feature of Alzheimer's disease.

A positive Elecsys pTau217 result indicates a high likelihood of having a positive amyloid PET/cerebrospinal fluid (CSF) result.

A negative Elecsys pTau217 result indicates a high likelihood of having a negative amyloid PET/CSF result.

An indeterminate pTau217 result indicates uncertainty on the amyloid PET/CSF result.

The pTau217 result should be used in the diagnostic pathway in conjunction with other clinical information.

About Roche in Alzheimer's disease

With more than two decades of scientific research in Alzheimer's, Roche is working toward a day when we can detect the disease early and stop its progression to preserve what makes people who they are. Today, the company's Alzheimer's portfolio spans investigational medicines for different targets, types and stages of the disease. This includes trontinemab, an innovative Brainshuttle™ anti-amyloid treatment that is specifically engineered to cross the blood-brain barrier. On the diagnostics side, it also includes approved and investigational tools, including digital and blood-based tests and CSF assays, aiming to more effectively detect, diagnose and monitor the disease. Yet the global challenges of Alzheimer's go well beyond the capabilities of science, and making a meaningful impact requires collaboration both within the Alzheimer's community and outside of healthcare. We will continue to work together with numerous partners with the hope we can transform millions of lives.

About Breakthrough Device Designation

The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. This program is designed to expedite the development and review of these medical devices.

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

[1] Alzheimer's Disease International. Internet; cited March 24, 2024.
[2] Janelidze et al. Nat Med. 2020:26(3):379-386; Karikari et al. Lancet Neurol. 2020:19(5):422-433; Palmqvist et al. JAMA. 2020:324(8):772-781; Thijssen et al. Lancet Neurol. 2021:20(9):739-752; Mattsson-Carlgren et al. JAMA Neurol. 2023:80(4):360-369

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