

Roche announces collaboration with Lilly to enhance early diagnosis of Alzheimer's disease

- **Roche and Lilly will collaborate on the development of Roche Diagnostics' Elecsys® Amyloid Plasma Panel.**
- **The Elecsys Amyloid Plasma Panel has demonstrated clinical performance and is currently undergoing additional investigation to ensure clinical validation.**
- **Once approved, it could help healthcare professionals streamline the journey to diagnosis for more patients.**

Basel, March 22, 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has entered into a collaboration with Eli Lilly and Company to support the development of Roche's Elecsys Amyloid Plasma Panel (EAPP). The EAPP is an innovative blood test that aims to facilitate the earlier diagnosis of Alzheimer's disease.

Today, barriers to early and accurate diagnosis of Alzheimer's exist across the globe, with up to 75% of people living with the symptoms of Alzheimer's but without a diagnosis. Those who have received a diagnosis waited, on average, 2.8 years after symptom onset¹. To address the growing strain that Alzheimer's is putting on healthcare systems, it will be essential to make a person's journey to diagnosis faster and more accessible. This will ultimately enable access to appropriate new therapies as they become available.

This collaboration is aligned to both Roche and Lilly's shared objective to support patients by improving the journey to a timely and accurate diagnosis and treatment. If approved, the EAPP test would be an additional tool to identify low likelihood of amyloid pathology in symptomatic patients and determine whether they should proceed to further evaluation and testing that may confirm a diagnosis.

"We are excited to be collaborating with Lilly on such an important area of unmet medical need," said Matt Sause, CEO of Roche Diagnostics. "Today, over 55 million people are living with dementia and this is projected to increase to nearly 140 million by 2050². Collaboration is essential to ensure these people receive a timely and accurate diagnosis. The Elecsys Amyloid Plasma Panel has the potential to streamline a person's journey to diagnosis and, therefore, access to future treatment options."

"We are pleased to be joining Roche to support the development of yet another potential diagnostic tool," said Mark Mintun, Lilly group vice president – Neuroscience R&D and president, Avid Radiopharmaceuticals. "We look forward to the robust data and continued collaboration across the field that will be critical to accelerate the ecosystem to aid in a timely and accurate diagnosis of Alzheimer's."

In July, Roche announced that the U.S. Food and Drug Administration granted the EAPP Breakthrough Device Designation.

In December 2022, Roche also received FDA 510(k) clearance for its Elecsys® beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys® Phospho-Tau (181P) CSF (pTau181) assays, which identify Alzheimer's pathology in its early symptomatic stage.

About the Elecsys Amyloid Plasma Panel

The Elecsys Amyloid Plasma Panel measures phosphorylated Tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay in human blood plasma. Elevations in pTau181 occur in early stages of Alzheimer's, while the presence of *APOE4* constitutes the most common genetic risk factor for Alzheimer's disease. The result is intended for consideration in conjunction with other clinical information to advise for further confirmatory testing with amyloid positron emission tomography (PET) or cerebrospinal fluid (CSF) testing. Patients testing negative with the Elecsys Amyloid Plasma Panel are unlikely to be amyloid positive and should be investigated for other causes of cognitive decline.

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. It also includes approved and investigational tools, including digital and blood-based tests and cerebrospinal fluid (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 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 thirteenth 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.

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References

[1] Life Expectancy Following Diagnosis Of Alzheimer's Disease Depends On Age At Diagnosis, Johns Hopkins Bloomberg School of Public Health, November 18, 2002, <https://publichealth.jhu.edu/2002/alzheimer-age>

[2] World Health Organization. Dementia. <https://www.who.int/news-room/fact-sheets/detail/dementia>

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