Media & Investor Release

Roche receives CE mark for new blood test to detect Alzheimer's pathology: Elecsys® plasma phosphorylated-tau 217 (pTau217)

- **Elecsys® pTau217 is the first blood test for Alzheimer's disease pathology with a single-assay design, intended to rule in and rule out amyloid pathology across primary and secondary care, offering faster diagnosis for millions of patients around the world.[1,2,5]**
- **While maintaining accuracy comparable to spinal fluid diagnostics against the gold standard PET-CT scans, the Elecsys® pTau217 test offers a more convenient, minimally invasive alternative via a routine blood draw.[1,2,4,7,8,11]**
- **Diagnosing dementia currently takes 3.5 years on average,[11] and an estimated 75% of people living with dementia remain undiagnosed.[6,9,11] Elecsys® pTau217 offers a simple blood test to aid in earlier, more accessible Alzheimer's disease diagnosis for millions of patients around the world.[1,2,4,5,7,8]**

Basel, 12 May 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that it has received CE Mark for Elecsys® pTau217, a blood test developed in collaboration with Eli Lilly and Company and designed to measure the phosphorylated Tau (pTau) 217 protein, an indicator of amyloid pathology and a hallmark of Alzheimer's disease.[1,2,4,7,8] The same cutoffs (high and low) of the blood test can be used across primary and secondary care settings, to rule in or rule out amyloid pathology in people presenting with symptoms or complaints of cognitive decline.[1,2,4,5] The early detection of the amyloid pathology is critical for Alzheimer's diagnosis and treatment, as it enables individuals, families, and caregivers to understand the cause of symptoms, access appropriate care, and actively contribute to the planning of next steps.[3,4,5,9,10]

"The launch of pTau217 marks a significant step in providing a simple, blood-based tool to diagnose Alzheimer's much earlier in the patient journey," said Matt Sause, CEO of Roche Diagnostics. "Today, many people face a long and difficult path to a diagnosis, often relying on specialised care and costly procedures. By bringing this advanced test into routine care, we are helping physicians to support patients and families with an earlier assessment that is critical for timely intervention, while reducing pressure on healthcare systems."

"For millions of families navigating the uncertainty of Alzheimer's, a timely diagnosis is the first and most critical step toward meaningful care," said Carole Ho, M.D., Executive Vice President and President, Lilly Neuroscience. "Lilly's collaboration with Roche on the Elecsys pTau217 assay was driven by a shared commitment to bringing this innovation into routine practice, overcoming complexity in testing and enabling patients to make informed decisions about the future."

Barriers to early and accurate diagnosis of Alzheimer's disease exist worldwide.[9,6,11] An estimated 75% of people living with dementia remain undiagnosed,[6,9,11] and those who are diagnosed typically wait an average of around 3.5 years after cognitive decline symptoms are first noticed.[3,4,6,9] With Alzheimer's disease representing the most common cause of dementia, improving access to tests that detect Alzheimer's-related brain changes is critical to speeding up diagnosis.[3,4,8,9,10] Current methods to confirm amyloid pathology – such as positron emission tomography (PET) scan and cerebrospinal fluid (CSF) assessment – can be difficult to access, expensive, and can be perceived as more invasive than a simple blood test.[7,8] The pTau217 assay contributes to addressing the undiagnosed population, with reliable detection of AD pathology in individuals with early cognitive decline symptoms.[1,2,5,8]

The Elecsys® pTau217 CE Mark was granted based on data from retrospective studies of a real-world population at the earliest stages of Alzheimer's (Subjective Cognitive Decline, Mild Cognitive Impairment and Mild Dementia), a point where individuals may notice memory changes but still live independently.[1,2,5,8] This focus ensures the test performs where it is needed most: at the dawn of the disease, when timely intervention has the greatest potential to preserve independence and slow the progression of decline.[3,4,9,10]

Further information will be presented at today's Roche Diagnostics Day 2026, starting at 14:00 CET.

About Elecsys® pTau217

A positive Elecsys® pTau217 blood test result indicates a high likelihood of amyloid pathology, a hallmark of Alzheimer's disease.[1,2,4,7,8] This can guide primary care clinicians to make timely referrals and provide specialists with the actionable data needed to advance patient evaluation and management.[2,3,4,8,9,10]

A negative result indicates a low likelihood of amyloid pathology, meaning clinicians may be able to rule out Alzheimer's disease and avoid further invasive CSF or PET investigations, helping to preserve specialist resources by shifting clinical focus to other potential causes of cognitive symptoms.[1,2,4,7,8] An indeterminate result requires additional testing to establish a diagnosis.[4,8] Elecsys® pTau217 should be used in conjunction with other clinical information.[3,4,8]

The Elecsys® pTau217 assay is clinically robust, supporting flexible workflows and sample handling aligned with routine processes.[1,2,5,8] Data support its potential to refine diagnosis by providing a single, robust biomarker that is broadly available across Roche's large installed base of instruments with a high-throughput, full-automation assay.

Following CE Mark approval, this simple and convenient blood test will leverage Roche's broad installed base of instruments across countries accepting the CE mark, positioning Elecsys® pTau217 for rapid and wide implementation in routine practice.

This scale makes it easier for laboratories to bring accurate, minimally invasive Alzheimer's testing closer to patients and clinicians throughout countries accepting CE mark, with the potential for expansion to the US, subject to FDA approval later this year.

About Roche in Alzheimer's

With more than two decades of scientific research in Alzheimer's, Roche is working towards a day when we can detect and treat the condition earlier, so we can slow, stop or even prevent its progression and preserve what makes people who they are. Today, Roche's Alzheimer's disease portfolio spans investigational diagnostics and medicines for different targets, types and stages of the disease.

In pharma, trontinemab is an investigational Brainshuttle bispecific 2+1 amyloid-beta targeting monoclonal antibody specifically engineered for enhanced brain access, enabling rapid reduction of amyloid in people with Alzheimer's disease (AD), and is currently being investigated in two Phase 3 clinical studies in early AD. Nivegacetor is a highly potent and selective oral gamma-secretase modulator (GSM) that alters amyloid precursor protein (APP) processing to prevent amyloid accumulation and halt plaque formation, and is currently in Phase 2 clinical development for AD.

In diagnostics, Roche offers one of the broadest portfolios of biomarker assays, including the blood-based Elecsys® pTau217, Elecsys® pTau181 and Elecsys® ApoE4 tests, in addition to CSF assays and digital solutions. These enable more effective and timely detection, diagnosis, and monitoring of the disease across the care pathway. The company also provides a wide range of research-use-only (RUO) assays that advance scientific understanding and support future innovation.

Addressing the global burden of Alzheimer's requires more than innovative tests and treatments. This is why Roche partners with clinicians, scientists, patient advocates, policymakers and health systems to help ensure that advances in Alzheimer's research translate into benefits for millions of people worldwide.

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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