Investor Update

Roche receives FDA clearance for Elecsys® pTau217, advancing Alzheimer's disease assessment across primary and specialty care

- **First and only FDA-cleared, single-biomarker blood test supporting both rule-in and rule-out assessment of amyloid pathology across primary and specialty care settings**
- **The test delivers consistency across clinical settings by using the same validated cutoffs in primary and specialty care**
- **Designed for broad implementation across Roche's installed base of more than 4,500 cobas laboratory instruments in the U.S. supporting access through existing laboratory infrastructure**

Basel, August 24, 2026 – Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has cleared the Elecsys® Phospho-Tau (217P) Plasma (pTau217) blood test, providing clinicians across primary and specialty care with a single blood-based option to aid in identifying amyloid pathology associated with Alzheimer's disease in individuals 55 years and older with signs, symptoms, or complaints of cognitive decline.[4] Developed in collaboration with Eli Lilly and Company, Elecsys pTau217 is the first and only FDA-cleared, single-biomarker blood test that supports both rule-in and rule-out assessment of amyloid pathology using the same validated clinical cutoffs across primary and specialty care settings.

"FDA clearance of Elecsys pTau217 marks an important milestone in Alzheimer's disease diagnosis and underscores Roche's continued leadership in advancing innovative solutions that can help patients get answers sooner," said Dan Malarek, President and CEO of Roche Diagnostics North America. "As the first and only FDA-cleared, single-biomarker blood test supporting both rule-in and rule-out assessment of amyloid pathology, Elecsys pTau217 has the potential to transform how Alzheimer's is assessed across primary and specialty care. This kind of innovation can help bring diagnostic evaluation closer to patients and give clinicians greater confidence in determining the right step in their care."

The assay provides positive, intermediate and negative result categories to support assessment of the likelihood of amyloid pathology. Results are interpreted in conjunction with clinical information and other relevant findings as part of the Alzheimer's disease diagnostic pathway.[4]

Healthcare providers across primary and specialty care now have access to the first and only FDA-cleared, single-biomarker blood test designed to support both rule-in and rule-out assessment of amyloid pathology. The test is designed for use across Roche's more than 4,500 cobas® laboratory instruments in the United States, enabling broad access through existing laboratory infrastructure.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland

Investor Relations
email:
investor.relations@roche.com

Tel. +41 61 68-88880
www.roche.com

Closing the Alzheimer's diagnosis gap

An estimated 75% of people living with dementia remain undiagnosed,[2] and those who are diagnosed often experience years of uncertainty after symptoms first appear.[1,3] Traditional approaches used to assess amyloid pathology, including positron emission tomography (PET) imaging and cerebrospinal fluid (CSF) testing, may be costly, invasive and difficult to access outside specialty centers.[6,7]

The Elecsys pTau217 blood test helps address these barriers by providing a minimally invasive blood-based option that can be incorporated into existing clinical and laboratory workflows. The test may help clinicians assess the likelihood of amyloid pathology earlier in the disease and diagnostic pathway and identify patients who should be considered for additional evaluation or specialist referral.

"For millions of families navigating the uncertainty of Alzheimer's disease, 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 Elecsys pTau217 was driven by a shared commitment to bringing one blood test into both primary care, where most patients with cognitive complaints are first seen, and specialty care, helping close the gap between symptoms and answers."

Supporting clinical decision-making

Following FDA clearance, Elecsys pTau217 may help healthcare providers and health systems:

- **Support clinical decision-making across primary and specialty care settings** through a single-biomarker blood test that provides positive, intermediate or negative amyloid pathology results to aid clinical assessment of amyloid pathology.
- **Help identify appropriate next steps** by distinguishing patients with a high or low likelihood of amyloid pathology and those who should be considered for further testing.
- **Support a more efficient diagnostic pathway** by providing a minimally invasive blood-based option that may help clinicians determine when additional evaluation, including PET imaging or CSF testing, is appropriate.

"For decades, clinicians have faced significant challenges in accurately diagnosing Alzheimer's disease in its early stages. While PET imaging and cerebrospinal fluid biomarkers can confirm amyloid pathology in patients with cognitive impairment, these approaches may be costly, invasive and not readily accessible for many patients," said Jared R. Brosch, M.D., Neurologist, Indiana University Health. "Advances in blood-based biomarkers have the potential to transform the diagnostic pathway by expanding access to evaluation for Alzheimer's across a variety of care settings. As these tools become available, clinicians may be able to evaluate more patients earlier in the disease course, improving diagnostic confidence and helping patients and their families make more informed decisions at a critical time."

A simple, scalable approach to Alzheimer's testing

Evaluated in individuals 55 years and older with signs, symptoms or complaints of cognitive decline associated with Alzheimer's disease, Elecsys pTau217 demonstrated high agreement with amyloid PET imaging, providing clinicians with a minimally invasive option for assessing amyloid pathology.[5]

As a single-assay solution, Elecsys pTau217 simplifies laboratory implementation by using one biomarker and one set of validated clinical cutoffs to support both rule-in and rule-out assessment of amyloid pathology. Roche refers to this approach as the "Power of One"— one assay, one biomarker and one set of validated clinical cutoffs designed to simplify Alzheimer's assessment while expanding access to blood-based testing.

Elecsys pTau217 is not intended to be used as a stand-alone test. Results should be interpreted in conjunction with other diagnostic tools and clinical information. The safety and effectiveness of the assay have not been established for predicting development of dementia or other neurologic conditions or for monitoring the effect of therapeutic products.[4]

Designed for broad implementation in existing laboratory workflows

With more than 4,500 Roche cobas® instruments already installed in U.S. clinical laboratories, Elecsys pTau217 is designed to integrate into existing laboratory workflows without requiring additional instrumentation, supporting rapid implementation and broad access following FDA clearance.

For healthcare systems managing the growing burden of Alzheimer's, broader access to blood-based testing may help support more efficient diagnostic pathways, optimize referral decisions and make better use of limited specialist resources.

Advancing Roche's leadership in Alzheimer's disease

The FDA clearance of Elecsys® pTau217 represents an important milestone in Roche's continued leadership and commitment to advancing earlier diagnosis and treatment of Alzheimer's disease. As the first and only FDA-cleared, single-biomarker blood test supporting both rule-in and rule-out assessment of amyloid pathology in primary and specialty care, Elecsys pTau217 builds on more than two decades of Roche innovation in Alzheimer's disease.

Roche's Alzheimer's portfolio includes:

Diagnostics

- Elecsys® pTau217
- Elecsys® pTau181
- Elecsys® pTau181/Abeta42 ratio
- Elecsys® tTau/Abeta42 ratio

Research assays

- A portfolio of neurology research-use-only (RUO) assays supporting ongoing biomarker research

Medicines

- **Trontinemab**, an investigational Brainshuttle™ amyloid beta-targeting monoclonal antibody designed for enhanced brain delivery and currently being evaluated in two phase III studies in early Alzheimer's disease.
- **Nivegacetor**, an investigational, oral gamma-secretase modulator designed to reduce amyloid accumulation and currently in phase II development.

Together, these diagnostics and investigational medicines reflect Roche's strategy to advance earlier diagnosis and treatment of Alzheimer's disease.

About Roche in Alzheimer's disease

For more than two decades, Roche has been advancing research, diagnostics and medicines for Alzheimer's disease with the goal of helping people receive answers and access care earlier in the course of disease. The company works with clinicians, researchers, patient advocates, policymakers and healthcare systems worldwide to translate scientific advances into meaningful benefits for patients and families.

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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Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com