Media & Investor Release

Roche's Elecsys Amyloid Plasma Panel granted FDA Breakthrough Device Designation to enable a timely diagnosis of Alzheimer's disease

- **The Elecsys Amyloid Plasma Panel is intended to be used in conjunction with other clinical information in symptomatic patients who are being evaluated for Alzheimer's disease and other causes of cognitive decline.**
- **The Elecsys Amyloid Plasma Panel has the potential to ensure better identification of patients that require further confirmatory testing, supporting a more timely and accessible diagnosis.**
- **This minimally invasive blood-based biomarker test can help to streamline a patient's journey, improving access to diagnosis and helping them better plan for the future.**

Basel, 19 July 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to the Elecsys® Amyloid Plasma Panel, an innovative new solution to enable Alzheimer's disease to be detected earlier. The Elecsys Amyloid Plasma Panel test detects and measures Alzheimer's disease biomarkers in blood plasma to indicate the need for further confirmatory testing for Alzheimer's disease. Roche is the first in-vitro diagnostics manufacturer to receive this designation for a blood-based biomarker test for Alzheimer's.

Alzheimer's disease is the most common form of dementia. Dementia affects more than 55 million people worldwide with more than 10 million new cases each year.[1] Barriers to early and accurate diagnosis of Alzheimer's disease exist across the globe – up to 3 out of 4 people living with symptoms of Alzheimer's disease have not been diagnosed[2], and those who have received a diagnosis, on average waited 2.8 years.

"The key to transforming the life of people with Alzheimer's disease is to diagnose as early as possible and intervene with the right care plans," said Thomas Schinecker, CEO of Roche Diagnostics. "Our new diagnostics test has the potential to streamline a patient's journey, improving speed and access toward a confirmatory diagnosis, giving people with Alzheimer's disease and their caregivers more time to plan and prepare for the future."

Currently, the diagnosis of Alzheimer's disease is largely based on clinical symptoms, including cognitive assessment, with a significant number of patients diagnosed when their disease has already advanced. The Elecsys Amyloid Plasma Panel will be the first qualitative test that combines the result of the phosphorylated Tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay in human plasma. Elevations in pTau occur in early stages of

Alzheimer's, while the presence of APOE E4 constitutes the most common genetic risk factor for Alzheimer's disease. 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.

The Elecsys Amyloid Plasma Panel has thus the potential to ensure better identification of patients that require further confirmatory testing. This could be done via PET scan or cerebrospinal fluid (CSF) testing, supporting a more timely and accessible diagnosis. In conjunction with other diagnostic tools and the work Roche is doing in developing potential new treatments, this could be an important building-block toward improved care and outcomes for people with Alzheimer's disease.

Roche has also received a Breakthrough Device Designation for the Elecsys® ß-Amyloid (1-42) CSF and Elecsys® Phospho-Tau (181P) CSF in vitro diagnostic immunoassays measuring ß-Amyloid (1-42) and Phospho-Tau concentrations in cerebrospinal fluid (CSF) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other causes of dementia.

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 pTau occur in early stages of Alzheimer's, while the presence of APOE E4 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 Alzheimer's disease

Alzheimer's is a progressive, fatal disease of the brain that gradually destroys memory, thinking skills and problem solving and impairs daily functioning such as the ability to manage one's own activities. Biological changes are believed to start decades before clinical symptoms of Alzheimer's become evident. Early signs and symptoms include memory loss, changes in mood or personality, decreased judgement, confusion, and challenges with problem-solving, finding the right word or familiar tasks.

Alzheimer's disease is the most common form of dementia. Dementia affects more than 55 million people worldwide with more than 10 million new cases each year. Up to 3 in 4 people with dementia worldwide have not been diagnosed.

Roche has an extensive Alzheimer's portfolio, including technology designed to more

effectively detect and diagnose Alzheimer's disease and monitor disease progression and multiple treatment approaches and molecules that may address key pathways of Alzheimer's disease. Data from two Phase III studies with Roche's investigational treatment, gantenerumab, in early Alzheimer's disease are anticipated in November 2022.

About the 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 personalised 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.

References

[1] "Dementia." *World Health Organization*, World Health Organization, 2 Sept. 2021, https://www.who.int/news-room/fact-sheets/detail/dementia#:~:text=Rates%20of%20dementia,and%20139%20million%20in%202050.
[2] Alzheimer's Disease International. "Adi - over 41 Million Cases of Dementia Go Undiagnosed across the Globe – World Alzheimer Report Reveals." *Alzheimer's Disease International (ADI)*, 21 Sept. 2021, https://www.alzint.org/news-events/news/over-41-million-cases-of-dementia-go-undiagnosed-across-the-globe-world-alzheimer-report-reveals/.

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