Media & Investor Release

Roche's Elecsys NfL test, an important aid for those living with multiple sclerosis, is granted FDA Breakthrough Device Designation

- **Roche Elecsys NfL is intended to aid in the detection of disease activity in adults with multiple sclerosis, supporting better disease management decisions.**
- **Elecsys NfL offers a minimally invasive testing option that is designed to provide rapid answers to patients and caregivers.**
- **NfL has the potential to provide patient insights for other neurological conditions such as Alzheimer's and Huntington's diseases.**

BASEL, November 9, 2023 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its Elecsys® Neurofilament Light Chain (NfL) test for multiple sclerosis (MS) received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA). The Elecsys NfL test is intended to be used as an aid in detection of disease activity in adults (18-55 years old) with relapsing-remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS), providing critical insights for disease management.

"Around 2.8 million people are estimated to live with multiple sclerosis.[1] After diagnosis, many face challenges with managing their disease due to significant gaps in access to testing. This can lead to missed opportunities to detect disease progression in support of treatment optimization," said Matt Sause, CEO of Roche Diagnostics. "We are excited about the potential Elecsys NfL has to improve outcomes for MS patients by offering a minimally invasive blood draw that can deliver rapid results."

Approximately 85% of MS cases are RRMS patients.[2] The majority of people diagnosed with RRMS eventually transition to SPMS, in which neurologic function worsens over time and disability increases. For patients with RRMS and SPMS, detection of disease activity is critically important in enabling them and their physicians to make the best possible decisions for the management of the disease.

Although the current spotlight for NfL's intended use is multiple sclerosis, increases in NfL concentrations have been reported in individuals with other neurodegenerative diseases, such as Alzheimer's and Huntington's diseases and in indications beyond neurology.

Elecsys NfL has the potential to help laboratories to scale MS testing on widely available, fully automated and standardized Roche cobas instruments with the confidence of in-vitro diagnostics quality, in a timely manner.

In July 2022, the FDA also granted Breakthrough Device Designation to Roche's Elecsys® Amyloid Plasma Panel, an innovative new solution to enable Alzheimer's disease to be detected earlier. Elecsys NfL receiving this designation is an important step as the organization strengthens its diagnostics neurology portfolio to meet growing societal needs.

About Elecsys NfL

Neurofilament Light Chain (NfL) is an abundant protein exclusively present in neurons and a sensitive indicator of neuroaxonal damage. Under normal conditions, NfL is released at low level from axons; however, this rate increases with age and following neuroaxonal damage. Therefore, abnormal, elevated levels of NfL can be detected in cerebrospinal fluid and blood in various acute and chronic neurological disorders. Although the current spotlight for NfL's intended use is multiple sclerosis, increases in NfL concentrations have been reported in individuals with traumatic brain injury, amyotrophic lateral sclerosis, frontotemporal dementia, Alzheimer's disease, Huntington's disease and other neurodegenerative diseases,[3] but also in other indications beyond neurology.

Roche's Elecsys NfL is intended to be used as an aid in detection of disease activity in human serum and plasma in adults (18-55 years old) with relapsing-remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS).

Once approved, broad global access to this testing will exist through the 75,000 Roche instruments currently available worldwide.

About the Breakthrough Device Designation

The FDA's 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 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] Walton C, King R, Rechtman L, et al. Rising prevalence of multiple sclerosis worldwide: Insights from the Atlas of MS, third edition. Mult Scler. 2020 Dec; 26 (14):1816-1821

[2] MS Society [Internet; cited 2023, Oct 25]
[3] Mayo Clinic [Internet; cited 2023, Oct 25]

For Further Information

Roche Diagnostics U.S. Media Relations

Cindy Zinkovich
1-317-931-8463
cindy.zinkovich@roche.com
us.mediarelations@roche.com