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News Release

Fujirebio enters the field of fully automated blood-based Alzheimer's disease biomarker testing with the release of the Lumipulse® G pTau 181 Plasma assay for Research Use Only

Gent, Belgium, Malvern PA, USA, and Tokyo, Japan, March 1st, 2022 – H.U. Group Holdings Inc. and its wholly-owned subsidiary Fujirebio today announced the availability of the Lumipulse G pTau 181 Plasma assay for the fully automated LUMIPULSE G immunoassay systems. This CLEIA (chemiluminescent enzyme immunoassay) assay allows for the quantitative measurement of Tau phosphorylated at threonine 181 in human plasma within just 35 minutes.

"The projected increase in the number of people suffering from dementia[1] poses significant public health challenges worldwide, of which early diagnosis will be of particular importance," said Goki Ishikawa, President and CEO of Fujirebio Holdings, Inc. *"Fujirebio is rising to this challenge with the availability of a fully automated plasma pTau 181 assay on our well recognized LUMIPULSE G platform. This breakthrough opens another new chapter in the field of neurodegeneration testing."*

With the launch of this new neurodegeneration assay, automated blood-based biomarker testing for Alzheimer's disease (AD), and testing for plasma pTau 181 in particular, may soon transition from research to clinical routine[2]. The assay is available for Research Use Only and will allow researchers and clinical research professionals to further study the clinical utility of this marker on the Lumipulse platform that has the required throughput and meets the regulatory requirements to support possible future routine use.

The Lumipulse G pTau 181 Plasma assay complements the panel of four key cerebrospinal fluid (CSF) assays (Aβ1-42, Aβ1-40, tTau and pTau 181) already available on the LUMIPULSE G platform. Today these four CSF parameters can provide essential information on the presence of amyloid and tau pathology in neurodegenerative disease. There is hope that blood-based testing can become an even simpler, more accessible, and more scalable approach to help support the diagnosis of AD. The plasma pTau 181 marker also has the potential to further advance the development of disease-modifying treatments by streamlining patient eligibility for clinical trials and monitoring of patients on such future treatments[3-4].

The development of the Lumipulse G pTau 181 Plasma assay will be accelerated with support from the Diagnostics Accelerator at the Alzheimer's Drug Discovery Foundation (ADDF) and Flanders Innovation & Entrepreneurship (VLAIO).

About Fujirebio

Fujirebio, a member of H.U. Group Holdings Inc., is a global leader in the field of high-quality in vitro diagnostics (IVD) testing. It has more than 50 years' accumulated experience in the conception, development, production and worldwide commercialization of robust IVD products.

Fujirebio was the first company to develop and market CSF biomarkers under the Innogenetics brand over 25 years ago. Fujirebio remains the only company with such a comprehensive line-up of manual and fully automated AD assays and consistently partners with organizations and clinical experts across the world to develop new pathways for earlier, easier and more complete neurodegenerative diagnostic tools. More information can be found at www.fujirebio.com/alzheimer.

About the Diagnostics Accelerator at the Alzheimer's Drug Discovery Foundation

The Diagnostics Accelerator, created in July 2018, is a partnership of funders with funding commitments totaling nearly $50 million over three years from partners including ADDF Co-Founder Leonard A. Lauder, Bill Gates, Jeff Bezos, MacKenzie Scott, the Dolby family, the Charles and Helen Schwab Foundation, The Association for Frontotemporal Degeneration, among others, to develop novel biomarkers for the early detection of Alzheimer's disease and related dementias.

This research initiative is dedicated to accelerating the development of affordable and accessible biomarkers to diagnose Alzheimer's disease and related dementias and advance the clinical development of more targeted treatments. Through translational research awards and access to consulting support from industry experts, this program will challenge, assist and fund the research community in both academia and industry to develop novel peripheral and digital biomarkers.

References:

1. GBD 2019 Dementia Forecasting Collaborators, Lancet Public Health, 2022; S2468-2667(21)00249-8.
2. Teunissen *et al*., Lancet Neurol, 2022; 21(1): 66-77.
3. Cummings *et al*., J Prev Alzheimers Dis 2021; 8(4): 398-410.
4. Cummings *et al*., Alzheimers Dement (N Y) 2021; 7(1):e12179.

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