H.U.GROUP

News Release

Fujirebio Confirms its Engagement in Blood-based Alzheimer's Disease Biomarker Testing with the Launch of the Fully Automated Lumipulse® G β-Amyloid 1-42 and β-Amyloid 1-40 Plasma Assays for Research Use Only

Gent, Belgium, Malvern PA, USA, and Tokyo, Japan, March 30, 2022 – H.U. Group Holdings Inc. and its wholly-owned subsidiary Fujirebio today announced the availability of the Lumipulse G β-Amyloid 1-42 Plasma and Lumipulse G β-Amyloid 1-40 Plasma assays for the fully automated LUMIPULSE G immunoassay systems. These CLEIA (chemiluminescent enzyme immunoassay) assays allow for the quantitative measurement of β-amyloid$_{1-42}$ and β-amyloid$_{1-40}$ in human plasma within just 35 minutes.

"With the launch of these two new tests on our robust LUMIPULSE G platform, Fujirebio truly becomes an essential actor in the field of blood-based testing," said Goki Ishikawa, President and CEO of Fujirebio Holdings, Inc. *"Our cerebrospinal fluid-based neurodegeneration IVD tests are already used by laboratories for routine testing in many countries across the world for decades, and this release continues the new chapter that we started writing earlier this month, with the launch of the Lumipulse G pTau 181 Plasma."*

The two new automated blood-based biomarker assays are available for Research Use Only. They will allow researchers and clinical research professionals across the world to further study the clinical utility of the Aβ$_{1-42}$, Aβ$_{1-40}$ and the pTau 181 markers in Alzheimer's disease and related disorders on the LUMIPULSE G platform. This platform has the required throughput and meets the regulatory requirements to support possible future routine use of blood-based testing of these markers.

The Lumipulse G β-Amyloid 1-42 Plasma and the Lumipulse G β-Amyloid 1-40 Plasma assays, together with the already available Lumipulse G pTau 181 Plasma assay, complement the panel of four key cerebrospinal fluid (CSF) assays (Aβ$_{1-42}$, Aβ$_{1-40}$, tTau and pTau 181) already available within the Lumipulse G as well as the INNOTEST® Neuro product portfolio. 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 Alzheimer's disease. Current research indicates that the plasma β-amyloid$_{1-42}$/β-amyloid$_{1-40}$ ratio has the potential to be used in clinical settings and within clinical trials to predict brain β-amyloid burden.[1-2] It could also be used as a tool to evaluate target engagement and efficacy of disease-modifying drugs.[3]

The development of the Lumipulse G β-Amyloid 1-42 Plasma and Lumipulse G β-Amyloid 1-40 Plasma assays has been supported by the 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.

References:

1. Palmqvist S, *et al*. EMBO Mol Med, 11(12): e11170, 2019.
2. Nakamura A, *et al*. Nature, 554(7691): 249-254, 2018.
3. Teunissen C, *et al.* Lancet Neurol, 21(1): 66-77, 2022.

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