News Release

Company name: H.U. Group Holdings, Inc.
Representative: Shigekazu Takeuchi, Chairman, President and Group CEO
Securities code: 4544 Prime Market, Tokyo Stock Exchange

Application for Manufacturing and Marketing Authorization in Japan for Blood-Based IVD Test to Aid in Identifying Amyloid Pathology Associated with Alzheimer's Disease

Tokyo, Japan, November 25, 2025 --- H.U. Group Holdings, Inc., and its wholly-owned subsidiary, Fujirebio Holdings, Inc. (hereinafter "Fujirebio") today announced that Fujirebio Inc., a subsidiary of Fujirebio, has filed its in-vitro diagnostic test (Class III) with the Ministry of Health, Labour and Welfare for measuring the concentrations of pTau 217 and β-Amyloid 1-42 using Fujirebio's fully automated Lumipulse® G1200 and Lumipulse® G600II instrument systems.

Accumulation of β-amyloid in the brain is considered one of the causes of Alzheimer's disease and is a target for antibody drugs indicated for the disease. By measuring pTau217 and β-amyloid 1-42 concentrations in plasma with this test, it is expected to help assess amyloid β accumulation (amyloid pathology) in the brain.

This test was approved by the U.S. Food and Drug Administration (FDA) in May 2025 as the first FDA cleared blood-based in vitro diagnostic test to aid to identify patients with amyloid pathology associated with Alzheimer's disease*, and sales have commenced. In addition, approval was obtained in India in June 2025 through a local partner company.

As part of its important global strategy, the H.U. Group will continue to expand its product lineup in the field of neurological diseases, including Alzheimer's disease, and further contribute to advancing diagnosis and treatment in this field.

Notes:

- The information on pharmaceuticals and medical devices described in this news release, including those under development, is provided for the purpose of disclosing management information and is not intended for advertising or promotional purposes.
- Please note that research reagents are not to be used for medical or clinical diagnosis in humans or animals.

* Press Release dated May 16, 2025 "Fujirebio receives marketing clearance for Lumipulse® G pTau 217/β-Amyloid 1-42 Plasma Ratio in-vitro diagnostic test as an aid to identify patients with amyloid pathology associated with Alzheimer's disease"

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