News Release

Company name: H.U. Group Holdings, Inc.
Representative: Goki Ishikawa, Representative Executive Officer, President and Group CEO
Securities code: 4544 Prime Market, Tokyo Stock Exchange

Blood-Based pTau217 IVD Test Approved in Japan to Help Assess Amyloid β Accumulation in the Brain Associated with Alzheimer's Disease

Tokyo, Japan, November 11, 2026 --- H.U. Group Holdings, Inc., and its wholly-owned subsidiary, Fujirebio Holdings, Inc. today announced that Fujirebio Inc., a subsidiary of Fujirebio Holdings, has received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare for in vitro diagnostic test used to measure the concentrations of pTau217 in plasma using Fujirebio's fully automated Lumipulse® G1200 and Lumipulse® G600II instrument systems.

Application for manufacturing and marketing approval for this test was filed in November 2025*[1]. 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. Through approaches measuring the pTau217 concentration in plasma with this reagent, the results can be used to help assess amyloid β accumulation (amyloid pathology) in the brain.

The pTau217/β-Amyloid 1-42 plasma ratio IVD test is the first FDA-cleared blood-based test to aid in identifying patients with amyloid pathology associated with Alzheimer's disease*[2]. Fujirebio will continue to collaborate with relevant organizations worldwide and expand its product lineup in the field of neurological diseases, including Alzheimer's disease, to further contribute to advancing diagnosis and treatment in this field.

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

*[2] 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

About H.U. Group

H.U. Group was founded in 1950 and is headquartered in Tokyo, Japan. The company provides essential healthcare products and services worldwide and employs more than 10,000 people across the United States, Europe, and Japan. H.U. Group Holdings, Inc. (TSE: 4544) operates a diverse healthcare portfolio that includes Fujirebio, a global diagnostics company; SRL, one of Japan's leading clinical laboratory testing providers; and Nihon Stery, a specialist in medical sterilization services. Leveraging the strengths of its core businesses, H.U. Group advances its "Group Strategy by Disease Area" centered on the Patient Journey, with a particular focus on areas such as Oncology and NEURO.

In the field of *in vitro* diagnostics (IVD), Fujirebio delivers innovative, high-impact solutions worldwide, including the first FDA-cleared blood-based IVD test to aid in the diagnosis of Alzheimer's disease. The company also offers a flexible CRDMO model to diagnostic partners. In clinical laboratory testing and healthcare support services, SRL and Nihon Stery support healthcare providers throughout Japan, leveraging strong relationships with major medical institutions nationwide.

Guided by its mission to "create new value in healthcare and thereby contribute to human health and the future of medical care", H.U. Group leverages innovation and partnerships to address unmet medical needs and realize its vision of becoming "a GLOBAL H.U. Group". For more information, please visit https://www.hugp.com/en/.

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