February 16, 2026
J-Pharma Co., Ltd.

The IND Safety Review for JPH034 Has Been Completed, Advancing Toward Initiation of a Phase 1 Clinical Trial in the United States

We are pleased to announce that, with respect to the Investigational New Drug (IND) application for JPH034 for the treatment of multiple sclerosis submitted to the U.S. Food and Drug Administration (FDA), we received notification from the FDA, dated February 12 (U.S. time), that the safety review has been completed and that the clinical trial plan submitted by the Company may proceed. The Company is now authorized to initiate clinical trials of JPH034 in the United States.

JPH034 is a LAT1 inhibitor with high brain penetration. By crossing the blood–brain barrier and targeting microglia, the immune cells in the central nervous system, JPH034 has the potential to offer a novel therapeutic approach for non-relapsing secondary progressive multiple sclerosis, a disease area in which treatment options with existing therapies remain limited.

Multiple sclerosis is a chronic inflammatory demyelinating disease of the central nervous system that most commonly affects young adults and is designated as an intractable disease by Japan's Ministry of Health, Labour and Welfare. The average age at diagnosis is approximately 32 years. More than 60,000 people worldwide are newly diagnosed each year, and the total number of patients is estimated to be approximately 2.9 million globally. About 85% of patients initially present with relapsing-remitting multiple sclerosis, which progresses through repeated relapses and remissions and transitions to secondary progressive multiple sclerosis after 10 to 15 years.

JPH034 has been supported by its selection for the Fast Forward Research Grant from the U.S. National Multiple Sclerosis Society, which is widely recognized for its highly competitive and rigorous evaluation standards, with funding of USD 600,000. In addition, the Company has been selected for the Drug Discovery Venture Ecosystem Program of the Japan Agency for Medical Research and Development (AMED) and is advancing development with subsidies of up to JPY 2.0 billion.

With respect to intellectual property, the Company has obtained an exclusive global license

to the patents owned by Georgetown University in the United States covering LAT1 inhibitors for central nervous system inflammatory diseases, including multiple sclerosis. Through this licensing arrangement, the Company is strengthening its exclusive position in the development and commercialization of JPH034.

The Company has initiated a global Phase III clinical trial of its LAT1 inhibitor, nanvuranlat, for the treatment of biliary tract cancer and is now in the final stage of clinical development toward regulatory approvals in major markets worldwide. In addition, JPH034, which represents our second key development asset, has now advanced into the clinical stage in the United States as the first step in its global development. Leveraging its proprietary drug discovery platform, the Company aims to deliver innovative medicines to patients worldwide and to achieve sustainable and transformative growth as a Japan-origin global drug discovery company.

About J-Pharma Co., Ltd.

J-Pharma Co., Ltd. aims to pursue new possibilities for SLC transporters and contribute to the hope and health of people worldwide through the development of innovative new drugs that address unmet medical needs. Under this mission, the Company has focused on LAT1 (L-type amino acid transporter 1), one of the SLC transporters discovered by the Company's founder and is advancing the development of LAT1 inhibitors to address the needs of patients with cancer and autoimmune diseases, where existing drugs are insufficient.
For more information, please visit: https://www.j-pharma.com/en/

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