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SymBio Pharmaceuticals Limited
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Representative Director
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(Securities Code: 4582)

SymBio Announces First Patient In (FPI) in NIH-led Trial of IV BCV for Progressive Multifocal Leukoencephalopathy (PML)

TOKYO, Japan, June 9, 2026 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "the Company") today announced that the first patient has been enrolled (First Patient In: FPI) in a clinical trial of intravenous brincidofovir (IV BCV) for the treatment of progressive multifocal leukoencephalopathy (PML). This trial is being conducted under a clinical Cooperative Research and Development Agreement (CRADA) entered into with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH).

This clinical trial is underway at the NIH Clinical Center in Bethesda, Maryland, under the leadership of Irene Cortese, M.D., with the objective of evaluating the efficacy and safety of IV BCV in patients with PML.

PML is a severe brain disease caused by infection of the central nervous system by the JC virus. Currently, there is no established standard therapy. The disease most often occurs in patients with immunodeficiency or immunosuppression. Given its high mortality rate, the development of new therapeutic agents is eagerly awaited.

Fuminori Yoshida, President and CEO, commented: "We are very pleased to be able to work with the research team at NIH/NINDS to develop a treatment for PML, a field that remains largely unexplored. We are actively pursuing development in the field of neurodegenerative diseases, which includes our ongoing work to develop a treatment for multiple sclerosis."

The Company does not expect this matter to have a material impact on its consolidated financial results for the fiscal year ending December 2026.

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Note

Progressive Multifocal Leukoencephalopathy (PML)

PML is a severe, life-threatening brain disease caused by infection of the central nervous system by the JC virus (JCV), a member of the polyomavirus family. There is currently no established standard therapy. The disease most often occurs in patients with impaired or suppressed immunity, is associated with high mortality, and is characterized by a short interval from diagnosis to disease progression and death. Given the lack of standard treatments and the high mortality rate, the development of new therapeutic agents is eagerly awaited. SymBio has confirmed in collaborative mouse studies with The Penn State College of Medicine that IV BCV exhibits high activity against a polyomavirus used in the experiments, which belongs to the same virus family as JCV, the virus causing PML. These research findings by Dr. Aron Lukacher's group were published in the journal mBio in July 2024 (https://journals.asm.org/doi/10.1128/mbio.01049-24).

Cooperative Research and Development Agreement (CRADA)

A CRADA is a formal agreement that facilitates research and development collaborations between a federal laboratory and a non-federal partner, such as a private company or university. By entering into this agreement, partners can leverage government research infrastructure, intellectual property, and advanced scientific expertise to promote R&D aimed at practical application. This CRADA marks the Company's third agreement with the NIH. Under this CRADA, an investigator-initiated clinical trial led by the NINDS (National Institute of Neurological Disorders and Stroke), part of the NIH (National Institutes of Health), will be conducted to build clinical insights regarding the efficacy and safety of IV BCV for PML.

BCV's Business Strategy Based on Three Therapeutic Pillars

Since acquiring the global license to BCV in September 2019, SymBio has been conducting collaborative research with world-class research institutions to unlock BCV's potential in three therapeutic areas. Currently, in the first pillar of viral infections, the Company is conducting a global Phase 3 clinical trial targeting adenovirus infections following hematopoietic stem cell transplantation. In the second pillar of hematologic malignancies and solid tumors, preparations are underway for clinical trials targeting malignant brain tumors and head and neck cancers. In the third pillar of neurodegenerative diseases, development is progressing for progressive multifocal leukoencephalopathy and multiple sclerosis under the CRADA signed with NIH/NINDS. By concentrating management resources on these therapeutic areas and actively promoting global business expansion, SymBio aims to maximize the business value of BCV.