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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Initiates Global Phase 3 Trial of IV Brincidofovir for the Treatment of Adenovirus Infection Post-HSCT, Following Regulatory Approval in Three Major European Countries

Tokyo, Japan, October 6, 2025 - SymBio Pharmaceuticals Limited ("SymBio" or the "Company") today announced the initiation of SymBio's international, multicenter Phase 3 clinical trial of the intravenous formulation of brincidofovir ("IV BCV"). This follows the approval of the Company's Clinical Trial Application (CTA), which was submitted to the European Medicines Agency (EMA) in June of this year, by three European Union (EU) member states: Germany, France, and Italy. The trial will commence in other EU member states upon receipt of CTA approval from their respective national authorities.

The Company has initiated development of the world's first antiviral therapy for adenovirus infection after hematopoietic stem cell transplantation (HSCT), a condition for which there is currently no approved treatment. Following the achievement of Proof of Concept (POC) in the Company's Phase 2 trial conducted in the U.S., this global Phase 3 study aims to validate those findings and pursue a marketing application in the EU ahead of other regions. The study is designed to enroll 180 patients at approximately 80 major transplant centers across the EU, the U.S., the U.K., and Japan. A marketing application submission is planned for the second half of 2028. Preparations are also underway to initiate the trial in other regions, including the U.S., the U.K., and Japan.

Statement from Fuminori Yoshida, President and CEO: "There is currently no approved treatment for adenovirus infection after HSCT, and an effective therapy is urgently needed. This disease, which predominantly affects pediatric patients and has a high mortality rate, represents a critical challenge in clinical practice. We are committed to advancing the development of IV BCV as swiftly as possible to deliver it to patients in need."

The Company does not expect the information presented herein to have a material impact on its financial outlook for the fiscal year ending December 2025.

[Contact] Investor Relations Tel: +81(0)3 5472 1125

Note

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, our management resources and development efforts are centered on three therapeutic pillars: (1) viral infections post-HSCT, (2) hematologic and solid tumors, and (3) neurodegenerative diseases. By expanding our business globally, we aim to maximize the business value of BCV.
As the first indication within the first pillar of post-transplant infections, we have initiated a global Phase 3 clinical trial for adenovirus infection. For the second pillar, in the area of hematologic cancers, we have initiated a Phase 1b/2 clinical trial for NK/T-cell lymphoma, are currently enrolling patients, and aim to submit for regulatory approval in 2028. Furthermore, in the solid tumor domain, preparations are underway to initiate clinical trials for indications including brain tumors and head and neck cancer. In the field of neurodegenerative diseases, we plan to advance clinical trials targeting multiple sclerosis (MS) and progressive multifocal leukoencephalopathy (PML).