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

SymBio Achieves First Patient In (FPI) in Global Phase 3 Clinical Trial of IV BCV for Adenovirus Infection Following Hematopoietic Stem Cell Transplantation

Tokyo, Japan, March 17, 2026 – SymBio Pharmaceuticals Limited (hereinafter "SymBio") today announced that it has achieved First Patient In (FPI) in the United States in its global Phase 3 clinical trial of intravenous brincidofovir (IV BCV) for treatment of adenovirus (AdV) infection after hematopoietic stem cell transplantation (HSCT) (NCT07387367). This FPI was achieved at Cincinnati Children's Hospital Medical Center in Ohio, United States, by Michael Grimley, MD, Professor of Pediatrics, Medical Director, Bone Marrow Transplant and Immune Deficiency, Cancer and Blood Diseases Institute.

This trial will enroll 180 patients across approximately 80 sites in the United States and five major European countries, as well as other countries. With cooperation of leading transplant centers in North America and Europe, patient enrollment is expected to proceed steadily. SymBio aims to enroll 69 patients by the end of December 2026 and complete patient enrollment by the end of 2027. This pivotal registration study will, support a Marketing Authorization Application (MAA) submission.

Currently, no approved treatments for AdV infection after HSCT exist. The disease carries a high mortality rate, creating an urgent need for effective therapy. SymBio will steadily advance patient enrollment targeting submission of a marketing approval application by the end of 2028.

Statement from Fuminori Yoshida, President and CEO: "This trial represents our Company's first global Phase 3 clinical trial and serves as an important foundation for our global business development. We will work as an entire organization to deliver new treatment options to patients as soon as possible."

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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Notes

Adenovirus Infection Following HSCT

Management of viral infections after hematopoietic cell transplantation remains an area of high unmet medical need. Adenovirus infection in this population has high infectivity, especially in children and can be fatal. IV BCV demonstrated clinical activity in a Phase 2 clinical trial conducted in the United States, achieving proof of concept (POC) for antiviral activity. Based on results of that clinical trial, the design of this Phase 3 clinical trial was developed. With cooperation of leading transplant physicians, this global Phase 3 clinical trial has now been initiated.

For the results of the Phase 2 clinical trial, please refer to the June 30, 2025 press release, "SymBio Submits Clinical Trial Application for a Phase 3 Global Study Evaluating IV Brincidofovir for the Treatment of Adenovirus Infection after HSCT."
(Link: https://www.symbiopharma.com/en/news/pdf/20250630e.pdf)

BCV Business Strategy Based on Three Therapeutic Pillars

Since obtaining the global license for BCV in September 2019, SymBio has advanced collaborative research with world-class institutions to unlock its potential across 3 therapeutic areas: (1) viral infections after hematopoietic stem cell transplantation; (2) hematologic malignancies and solid tumors; and (3) neurodegenerative diseases. With respect to area (3), preparations are underway to initiate a clinical trial in the United States for treatment of progressive multifocal leukoencephalopathy (PML), a neurodegenerative disease for which there is no treatment and where new drug development is urgently needed. By pursuing development and commercialization globally across these three pillars, SymBio aims to maximize the value of the BCV franchise.