

November 17, 2025
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Obtains Clinical Trial Authorization in the United Kingdom for the Global Phase 3 Clinical Study of Intravenous Brincidofovir in Adenovirus Infection Following Hematopoietic Stem Cell Transplantation

Tokyo, Japan, November 17, 2025 - SymBio Pharmaceuticals Limited (“SymBio” or the “Company”) today announced that it has obtained clinical trial authorization from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for its ongoing global Phase 3 clinical study of intravenous brincidofovir (IV BCV) for adenovirus infection following hematopoietic stem cell transplantation (HSCT). This study is currently being conducted in four countries in the EU. The Company has also received approval from the Health Research Authority (HRA) and confirmation from a Research Ethics Committee (REC). With these approvals, the Company has started the study across the five major European markets (Germany, France, Italy, Spain, and the UK) and is proceeding with preparations for early patient enrollment.

In addition, the Company is in discussions with the US Food and Drug Administration (FDA) with the aim of initiating the study in the US in 2026. With US sites added to the five major European countries, the Company will work toward early patient enrollment targeting the first quarter of 2026.

There is no material impact on the consolidated financial outlook for the fiscal year ending December 2025.

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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 malignancies and solid tumors, and (3) neurodegenerative diseases. SymBio is focusing on its business globally to maximize the business value of BCV.