October 7, 2025
SymBio Pharmaceuticals Limited
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Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Submits Clinical Trial Application to the UK's MHRA for the Phase 3 Global Study Evaluating IV Brincidofovir for the Treatment of Adenovirus Infection After HSCT

Tokyo, Japan, October 7, 2025 – SymBio Pharmaceuticals Limited (hereinafter "SymBio" or the "Company") today announced that it has submitted a clinical trial application (CTA) to the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to initiate the Company's global Phase 3 clinical trial of intravenous brincidofovir (IV BCV) for adenovirus infection following hematopoietic stem cell transplantation in the UK. The global Phase 3 clinical trial has already begun in three major EU member countries (Germany, Italy, and France), following approval from the European Medicines Agency (EMA) and subsequent national authorizations.*

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.

* For further details, see the Company's press release dated October 6, 2025.

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Notes

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. For the first pillar, we have initiated a global Phase 3 clinical trial for adenovirus infection post-HSCT, and aim to submit an application for marketing approval in the second half of 2028. 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, within solid tumors, we are considering the initiation of clinical trials for indications such as 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) in the future.