October 28, 2025
SymBio Pharmaceuticals Limited
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Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Receives MHRA Approval of its Pediatric Investigation Plan, a Requirement for Initiating the Global Phase 3 Study Evaluating IV Brincidofovir for the Treatment of Adenovirus Infection Post-HSCT in the United Kingdom

Tokyo, Japan, October 28, 2025 – SymBio Pharmaceuticals Limited (hereinafter "SymBio" or the "Company") today announced that the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has approved the Company's Pediatric Investigation Plan (PIP). The approval is required for the initiation of the Company's global Phase 3 clinical study evaluating the intravenous formulation of brincidofovir (IV BCV) for the treatment of adenovirus infection following hematopoietic stem cell transplantation (HSCT).

The global Phase 3 clinical study has already commenced in four major EU member states—Germany, France, Italy, and Spain—following regulatory approvals received in those countries in October 2025. The Company's Clinical Trial Authorization application for the United Kingdom was submitted in October 2025 and is currently under agency review. With the MHRA approval of the PIP, the Company has made a significant advance toward initiating the study in the UK.

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

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Notes

About the Pediatric Investigation Plan (PIP)

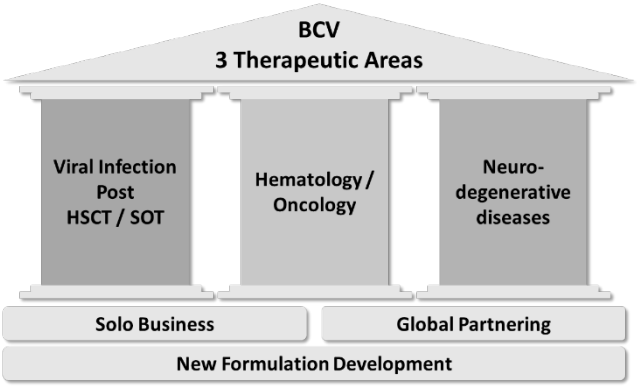
A Pediatric Investigation Plan (PIP) is a development plan aimed at ensuring that the necessary data from clinical studies in children are obtained to support the authorization of a medicine for the pediatric population. A PIP details specific clinical trials, implementation timelines, and any age groups for which a waiver is granted. Approval of a PIP is a prerequisite for submitting a Marketing Authorization Application to the MHRA. For an approved PIP that is appropriately completed, and which leads to a marketing approval, the market exclusivity period in the UK is extended by two years. This is in addition to the 10-year exclusivity for Orphan Drug designation, for a total market exclusivity period of 12 years.

The PIP approved by the MHRA is consistent with the plan approved by the European Medicines Agency in September 2025, confirming that the Company's pediatric development plan meets the requirements of both the UK and the EU.

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.

For the first pillar, we have initiated a global Phase 3 clinical trial for adenovirus infection post-HSCT and plan to submit a marketing application in the second half of 2028. For the second pillar, in the hematology-oncology area, we have initiated a Phase 1b/2 clinical trial for NK/T-cell lymphoma and are currently enrolling patients, with the goal of submitting a marketing application in 2028. In the solid tumor field, including brain tumors and head and neck cancer, we are advancing preparations toward



clinical trial initiation. For the third pillar, neurodegenerative diseases, we plan to advance clinical trials targeting multiple sclerosis (MS) and progressive multifocal leukoencephalopathy (PML) in the future.