October 15, 2025
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Receives Regulatory Approval in Spain to Proceed with its Phase 3 Global Study Evaluating IV Brincidofovir for the Treatment of Adenovirus Infection After HSCT

Tokyo, Japan, October 15, 2025 – SymBio Pharmaceuticals Limited (hereinafter "SymBio" or the "Company") today announced that it has received regulatory approval in Spain of the clinical trial protocol for the Company's ongoing global Phase 3 clinical trial evaluating the intravenous formulation of brincidofovir (IV BCV) for the treatment of adenovirus infection post-HSCT. With the addition of Spain, the clinical trial is active in four major European countries, including Germany, France, and Italy where the study has already commenced. In addition, the Company has submitted a Clinical Trial Authorization application in the United Kingdom, and plans to initiate the clinical trial in other EU member states as well as the UK within the current fiscal year.

Statement from Fuminori Yoshida, President and CEO: "We are now on track to begin the Phase 3 trial as planned, targeting submission of a New Drug Application in Europe in the second half of 2028."

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

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.