November 20, 2025
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Prioritizing and Focusing Resources on the Global Phase 3 Trial of IV Brincidofovir for Adenovirus Infection Post-HSCT - Portfolio Reprioritization

Tokyo, Japan, November 20, 2025 - SymBio Pharmaceuticals Limited ("SymBio" or the "Company") announced that, following a review of its IV brincidofovir (IV BCV) development portfolio at the board of directors meeting held today, SymBio will prioritize the ongoing global Phase 3 clinical trial in adenovirus infection post-HSCT and concentrate management resources on this study to maximize business value. In connection with this decision, SymBio will temporarily suspend the Phase 1b/2 clinical trial (NL01) in malignant lymphoma.

SyB V-1901 is an intravenous formulation of brincidofovir (IV BCV), an antiviral drug, believed to be effective against a variety of double-stranded DNA viral infections, as well as malignancies. As announced previously, the Company is initiating a global Phase 3 study for the treatment of adenovirus infection post hematopoietic stem cell transplantation (HSCT), with an RP2D selected based on the Company's Phase 2 study (ATHENA, NCT04706923).

SymBio plans to expand participation in the Phase 3 trial from the current four major EU countries plus the UK to nine EU countries, followed by phased expansion into additional regions including the US. Across the EU, the US, the UK, and Japan, the Company plans to activate approximately 80 trial sites and enroll approximately 180 patients.

The suspension of the NL01 study is due to challenges in recruiting eligible patients under the protocol. The Phase 1b portion of NL01 (NCT06761677) is a 3+3, dose-escalation the IV BCV, designed to determine a Phase 2 recommended dose (RP2D) in patients with relapsed or refractory lymphomas. Notably, this is a dose finding study, and a partial response (PR) was observed in one of the four patients who received the investigational drug, confirming anti-tumor effect in human. This supports further development of this drug in oncology with a revised study design.

Statement from Fuminori Yoshida, President and CEO: “By concentrating our management resources to execute the global Phase 3 study both rigorously and rapidly, we will work toward the earliest possible first new drug application for IV brincidofovir and strive to maximize our business value.”

SymBio will continue to pursue its BCV development strategy built on three therapeutic pillars—post-transplant viral infections, hematologic and solid tumors, and neurodegenerative diseases—to maximize pipeline value.

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

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Notes

Phase 1b/2 Clinical Trial (NL01) of Intravenous Brincidofovir (IV BCV) in Malignant Lymphoma

The Phase 1b portion was designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of IV BCV in patients with relapsed or refractory lymphomas, including NK/T-cell lymphoma, peripheral T-cell lymphoma (PTCL), and diffuse large B-cell lymphoma (DLBCL). The subsequent Phase 2 was planned as a multinational, multicenter study to evaluate the safety and efficacy of IV BCV at the recommended dose determined in Phase 1b in patients with relapsed or refractory NK/T-cell lymphoma.

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.