June 30, 2025

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

SymBio Submits Clinical Trial Application for a Phase 3 Global Study Evaluating IV Brincidofovir for the Treatment of Adenovirus Infection after HSCT

Tokyo, Japan, June 30, 2025 - SymBio Pharmaceuticals Limited (Headquarters: Tokyo, hereinafter "SymBio" or the "Company") today announced submission of a Clinical Trial Application (CTA) on June 27, 2025, to the European Medicines Agency for a Phase 3 clinical trial that will evaluate intravenous brincidofovir (IV BCV) for treatment of adenovirus infection after hematopoietic stem cell transplantation (HSCT).

SymBio acquired the global license for brincidofovir in September 2019 and subsequently established Phase 2 clinical proof-of-concept (POC) for antiviral activity of IV BCV in a Phase 2 clinical trial in the United States. A benefit-confirming randomized Phase 3 trial is expected to enroll about 180 patients across 80 sites in the European Union (EU), United States (US), United Kingdom (UK), and Japan. This trial is designed to support a marketing authorization application (MAA) submission to the European Medicines Agency in the second half of 2028.

In March 2025, SymBio convened an advisory board meeting with leading specialists from prominent hematopoietic stem cell transplantation centers in the EU, US, UK, and Japan to advance preparations for Phase 3 trial initiation. The meeting provided valuable insights on trial design, site selection, and other critical trial components. In addition, a feasibility study was conducted to refine and optimize the clinical trial plan.

Statement from Dr. Per Ljungman, Emeritus Professor of the Karolinska Institutet in Sweden, a member of the advisory board: "Adenovirus infection after hematopoietic stem cell transplantation can be a very serious condition, particularly in the current absence of treatment options. Physicians treating these infections have long awaited the development of new therapeutic agents. The initiation of this trial is a significant

and hopeful step forward for patients."

Statement of Mr. Fuminori Yoshida, President and CEO of SymBio: "Adenovirus infection after hematopoietic stem cell transplantation predominantly affects pediatric patients and has a high mortality rate, yet no effective treatments are currently available. We will strive hard to advance the study towards new drug approval as quickly as possible and at the same time, achieving profitability."

The Company does not anticipate the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 31, 2025.

Notes

1. **Adenovirus infection after hematopoietic stem cell transplantation (HCT)**

   Management of viral infections after hematopoietic cell transplantation remains an area of unmet medical need. Prominent among them, adenovirus infection has high infectivity, affects both pediatric and adult patients, and results in severe or even fatal outcomes due to absence of preventive or therapeutic options.

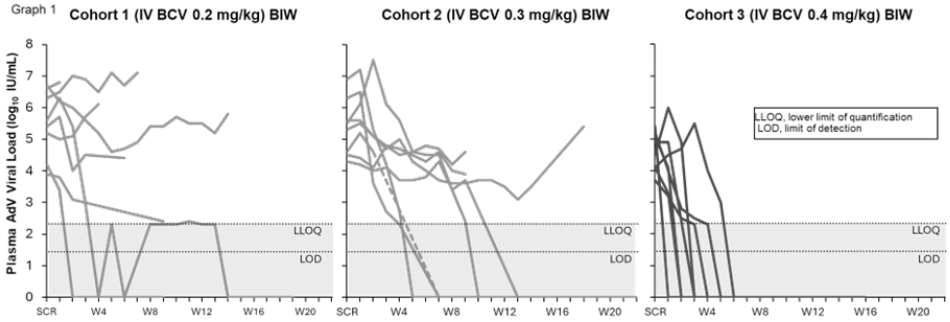
2. **Results of the Phase 2 Clinical Trial for Adenovirus Infection Using IV BCV**

   Results of SymBio's Phase 2 clinical trial in the United States were presented by Dr. Grimley, a pediatric transplant specialist from the University of Cincinnati, at the American Society of Hematology (ASH) Annual Meeting in December 2023. In Cohort 3 (0.4 mg/kg BCV up to maximum 20 mg, twice weekly), adenovirus clearance was achieved in all 10 of 10 cases, demonstrating strong antiviral activity of IV BCV. These POC data have been met with praise and expectations from transplantation and infectious diseases experts across the US and Europe.

Phase II Clinical Trial Data (Presented at the 2023 ASH Annual Meeting)

Table 1	Cohort 1 (IV BCV 0.2 mg/kg BIW) n=8	Cohort 2 (IV BCV 0.3 mg/kg BIW) n=9	Cohort 3 (IV BCV 0.4 mg/kg BIW) n=10
Mean duration of IV BCV treatment, weeks (Range)	5.1 (0.6-13.7)	8.8 (1.0-13.4)	5.1 (2.6-10.9)
Median duration of IV BCV treatment, weeks (IQR)	3.3 (4.7)	8.0 (6.0)	4.0 (2.9)
No. of patients who achieved viral clearance, n (%)	2 (25%)	3 (33%)	10 (100%)
Viral clearance upon or before completion of the initial 4-week IV BCV, n (%)	1 (13%)	1 (11%)	9 (90%)
Mean duration of IV BCV treatment, weeks (Range)	8.6 (3.4-13.7)	10.7 (5.4-13.4)	5.1 (2.6-10.9)
Median duration of IV BCV treatment, weeks (IQR)	8.6 (5.1)	13.1 (4.0)	4.0 (2.9)

Graph 1



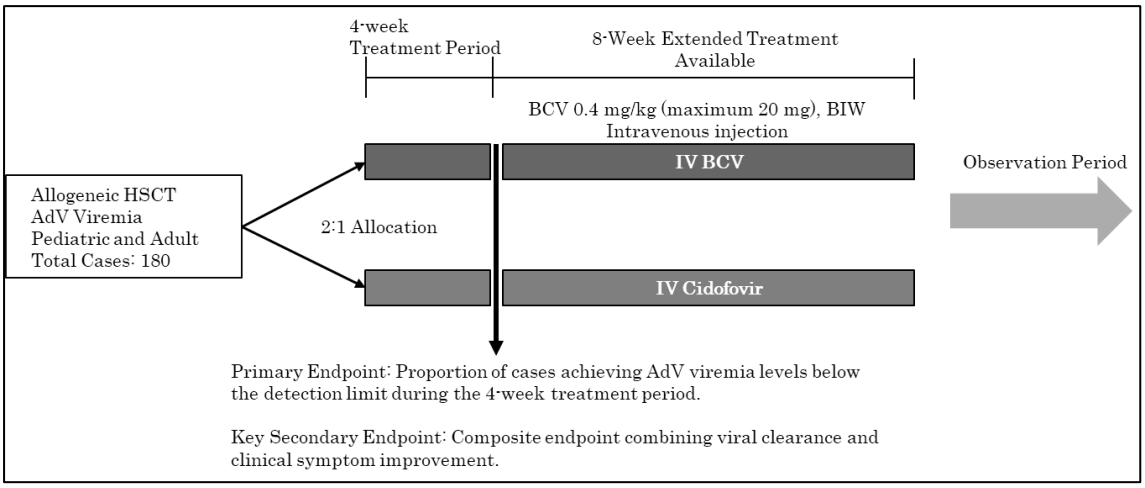
3. Design of the Trial and Clinical Trial Plan for IV BCV

The Clinical Trial Application (CTA) submitted on June 27, 2025 to the European Medicines Agency is for a Phase 3 clinical trial evaluating intravenous (IV) BCV for treatment of adenovirus infection in patients who have undergone hematopoietic stem cell transplantation. The trial plans to enroll 180 patients across 80 sites in the EU, US, UK, and Japan. SymBio aims to submit a Marketing Authorization Application in the EU in the second half of 2028, followed by applications in other countries.

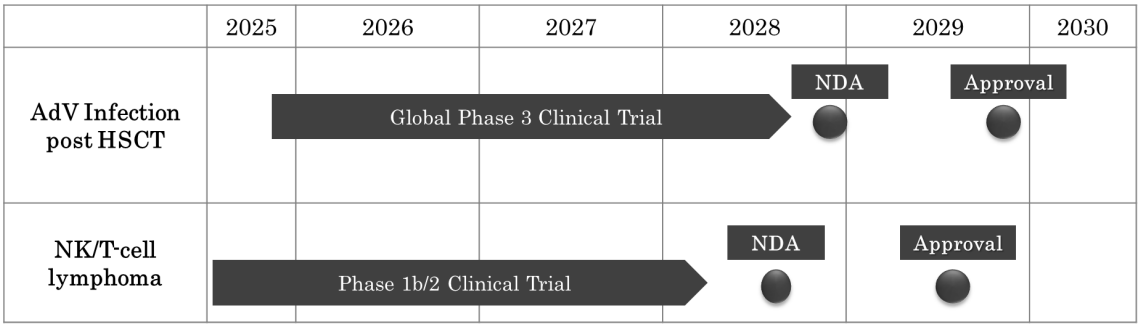
Trial Design

This randomized trial will evaluate IV BCV for post-HSCT adenovirus infection in both pediatric and adult patients. As with the Phase 2 clinical trial, patients will be enrolled based on blood adenovirus levels. IV BCV will be administered twice weekly for a duration of four weeks. The primary endpoint will be the proportion of patients whose blood adenovirus levels decrease to below undetectable levels four weeks after the start of treatment. Additionally, a key secondary endpoint will be a composite measure that combines virus clearance and improvement of associated clinical symptoms.

Trial Scheme

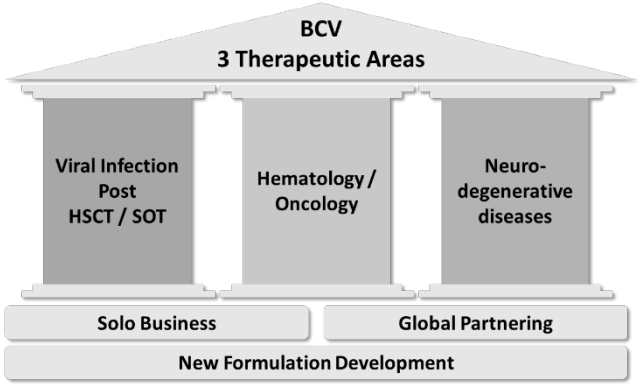


BCV Clinical Development Plan



4. SymBio's Business Strategy for BCV is Centered on Three Therapeutic Areas

Since acquiring the global license for BCV in September 2019, SymBio has been conducting collaborative research with world-class research institutions. These collaborations are evaluating BCV potential in three therapeutic areas: viral infections after hematopoietic stem cell transplantation; hematologic malignancies and solid tumors; and neurodegenerative diseases. By advancing development in these areas globally, SymBio aims to maximize the value of BCV.



In the area of hematologic malignancies, the Company is already conducting a Phase 1b/2 clinical trial for NK/T-cell lymphoma and is targeting a marketing authorization application in 2028.

In the area of solid tumors, SymBio is also exploring potential applications, including brain tumors.

SymBio is pursuing BCV's potential in multiple diseases across the three therapeutic areas. The Company's ability to develop a single drug that targets multiple diseases offers substantial flexibility, representing one of its core business strengths.