November 5, 2026
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Reaches Agreement with UK MHRA on Marketing Authorisation Application for Brincidofovir (BCV)

Tokyo, Japan, November 5, 2026 – SymBio Pharmaceuticals Limited ("SymBio" or the "Company") today announced that it has reached an agreement with the UK Medicines and Healthcare products Regulatory Agency (MHRA) to proceed with a marketing authorisation application for brincidofovir ("BCV") for the treatment of adenovirus infection following hematopoietic stem cell transplantation.

At the in-person scientific meeting with the MHRA on October 20, 2026, SymBio confirmed the data and other information required for the MHRA's review of the marketing authorisation application. Following the meeting, the Company began preparations to formally submit its application in January 2027.

It was agreed with the UK authorities that the application would be based on the combined data from the completed Phase 2 clinical trial of BCV for adenovirus infection following hematopoietic stem cell transplantation and data from the Compassionate Use Program (CUP) conducted to date. This agreement reflects growing recognition of BCV as an important treatment option in a serious disease area where treatment options are extremely limited. For innovative medicines intended to treat life-threatening diseases, early approval may be considered before comprehensive clinical data are available, provided that the benefits demonstrated to date are considered to outweigh the risks.

Related information available on our homepage (Japanese only):
https://www.symbiopharma.com/pipeline/brincidofovir-uk-news/

Key Development Pipeline

Pipeline	Indication(s)	Preclinical	Phase1	Phase2	Phase3	NDA	MA
SyB V-1901 IV Brincidofovir	Adenovirus (AdV) Infection post-HSCT: (UK)	Preparation started for MAA					
	Adenovirus (AdV) Infection post-HSCT: (EU, USA)	Global Phase 3 study					
	Progressive multifocal leukoencephalopathy (PML):	Phase 2 study					
	Glioblastoma (GBM):	Completed Preclinical/Preparing Phase 2 Study					

SymBio will focus on completing the process toward approval as rapidly as possible.

Statement from Fuminori Yoshida, President and CEO: “We will work closely with leading clinicians and regulatory authorities in each country. Recognizing the urgent need for treatment among patients in areas of unmet medical need, we are fully committed to delivering an innovative treatment option to healthcare settings worldwide as soon as possible.”

The Company does not expect this matter to have a material impact on its consolidated financial results for the fiscal year ending December 2026.

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Investor Relations

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Notes

UK Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency is an executive agency under the UK Department of Health and Social Care. It is responsible for the authorisation and safety of medicines and medical devices.

Marketing Authorisation Application System in the United Kingdom

BCV is now eligible for a marketing authorisation application to the UK Medicines and Healthcare products Regulatory Agency as a new medicine for which comprehensive clinical data are not yet available but are expected to be submitted in the near future.

About Clinical Trial for Adenovirus Infection Following Hematopoietic Stem Cell Transplantation

A global Phase 3 clinical trial is currently being conducted in the United States and Europe. As of end October 2026, 45 patients had been enrolled, showing steady and on-schedule patient enrolment. We are fully on track to complete the enrolment of 69 patients by the end of 2026 and 180 patients by the end of 2027 as planned. Regarding the global Phase 2 clinical trial, as announced on October 23, 2024, data demonstrating the clinical efficacy of the Phase 2a trial were presented at ID Week 2024 (October 16–19, 2024).

Press release: SymBio presents data from Phase IIa clinical trial showing clinical efficacy of IV BCV in treating symptoms of adenovirus infection

About SymBio Pharmaceuticals: BCV Business Strategy Centered on Three Therapeutic Areas

Since obtaining the global license for brincidofovir ("BCV") in September 2019, SymBio Pharmaceuticals has conducted joint research with world-leading research institutions in three therapeutic areas—double-stranded DNA virus infections, solid tumors, and neurodegenerative diseases—with the aim of unlocking BCV's potential in each area. SymBio is concentrating its management resources on the development of BCV, primarily for adenovirus infection following hematopoietic stem cell transplantation, progressive multifocal leukoencephalopathy ("PML"), glioblastoma, head and neck cancer, and EBV-associated gastric cancer. Through global business development, SymBio aims to maximize the business value of BCV.