

October 14, 2026
SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

**UK MHRA Accepts Briefing Book for Face-to-Face Scientific Advice Meeting on
Conditional Marketing Authorisation for Brincidofovir (BCV)**

Tokyo, Japan, October 14, 2026 – SymBio Pharmaceuticals Limited (“SymBio” or the “Company”) today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has formally accepted its Briefing Book as of October 13. This document was submitted in preparation for a face-to-face scientific advice meeting scheduled for October 20 at the MHRA offices in London. The meeting will focus on the Conditional Marketing Authorisation (CMA) application for brincidofovir (hereinafter, “BCV”) for the treatment of adenovirus infection following hematopoietic stem cell transplantation.

Adenovirus infection following hematopoietic stem cell transplantation is a life-threatening condition for which there are currently no approved antiviral treatments. Many existing antiviral drugs require a process called "phosphorylation" (driven by the virus's own enzymes) in order to become active and take effect. However, because adenoviruses lack these viral enzymes, typical antiviral drugs are less effective against them. In contrast, BCV and cidofovir (CDV) do not rely on viral enzymes; they can become active through phosphorylation using only the enzymes naturally present in human cells. This is the fundamental mechanism that allows both drugs to demonstrate high efficacy against adenoviruses. Furthermore, BCV avoids the nephrotoxicity (severe kidney damage) which is associated with CDV. Given these unique characteristics and the efficacy and safety demonstrated in clinical trials to date, there is a strong and growing demand from the medical community for the availability of BCV.

Statement from Minori Rosales, Corporate Vice President and Chief Medical Officer: “The Briefing Book for this upcoming face-to-face meeting with the MHRA is based on existing data for BCV. By positioning our ongoing Phase 3 trial, the BCV-PA-02 study, as a post-CMA confirmatory trial, we aim to enable the early provision of BCV to patients

who are eagerly awaiting this treatment.”

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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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.

Conditional Marketing Authorisation System in the United Kingdom

The UK Medicines and Healthcare products Regulatory Agency has established a Conditional Marketing Authorisation pathway for new medicines for which comprehensive clinical data are not yet available but are expected to be submitted in the near future. The pathway applies to medicines that address unmet medical needs, including those intended for:

- The treatment, prevention or diagnosis of seriously disabling or life-threatening diseases
- Emergency responses to threats to public health

The key criteria and requirements that must be met for CMA are:

- Available data must show that the therapeutic benefits of the medicine outweigh its potential risks
- The applicant must be able to provide comprehensive clinical data after authorization through post-approval obligations set by the MHRA
- The medicine addresses an unmet medical need

- The benefits of making the medicine available immediately to patients must outweigh risks associated with authorizing the medicine while the additional data is pending

Clinical Trial for Adenovirus Infection Following Hematopoietic Stem Cell Transplantation

The global Phase 3 clinical trial is currently being conducted in the United States and Europe. As of end September 2026, 35 patients had been enrolled. The Company expects enrollment of 69 patients by the end of 2026 and 180 patients by the end of 2027.

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.