

October 6, 2026
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

**SymBio Pharmaceuticals Commenced Discussions with the UK MHRA
Toward Obtaining Conditional Marketing Authorisation for Brincidofovir
(BCV)**

Tokyo, Japan, October 6, 2026 – SymBio Pharmaceuticals Limited (“SymBio” or the “Company”) today announced that it has commenced discussions with the UK Medicines and Healthcare products Regulatory Agency (MHRA) toward obtaining Conditional Marketing Authorisation (CMA) for brincidofovir (hereinafter, “BCV”) for the treatment of adenovirus infection following hematopoietic stem cell transplantation.

The commencement of these discussions represents an important development in the area of adenovirus infection following hematopoietic stem cell transplantation, a serious disease for which treatment options are extremely limited. The CMA is an innovative regulatory framework in the UK that enables early market access for innovative medicines intended to treat life-threatening diseases, even before comprehensive clinical data become available, provided that the benefits currently demonstrated are considered to outweigh the risks. Utilization of this system is intended to deliver medicines supported by medical evidence to clinical practice as soon as possible and provide relief to patients whose conditions are difficult to manage under existing treatment approaches. Following authorization, continued data collection and rigorous monitoring of safety and efficacy are required.

In clinical practice, significant challenges remain, including cases in which existing antiviral therapies do not provide an adequate treatment response and cases in which continued administration is difficult from a safety perspective. Dr. Robert Wynn, an authority on adenovirus infection following hematopoietic stem cell transplantation, has pointed out that, given the limited treatment options currently available, the highest

priority should be placed on providing relief to patients who cannot wait until the completion of clinical trials. Dr. Wynn has strongly called for every effort to be made to secure early access. The commencement of these discussions is based on the urgent requests of clinicians addressing this significant unmet medical need, as well as constructive dialogue with the regulatory authorities.

While advancing the process toward obtaining CMA, SymBio will also focus on completing the ongoing global Phase 3 clinical trial as rapidly as possible and establishing robust, medically valid evidence.

Statement from Fuminori Yoshida, President and CEO: “We will work closely with leading clinicians and regulatory authorities in each country to overcome the significant barrier posed by this unmet medical need. We are fully committed to completing the ongoing Phase 3 trial as rapidly as possible and delivering an innovative treatment option to medical settings around the world at the earliest opportunity.”

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 system for new medicines for which comprehensive clinical data are not yet available but are expected to be submitted in the near future. The system 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 following requirements must be met for authorisation:

- The benefits of the medicine outweigh its risks
- It is expected that comprehensive clinical data can be submitted after authorisation
- The medicine addresses an unmet medical need
- Even after considering the risks associated with the need for additional data, the benefit of making the medicine immediately available to patients outweighs those risks

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 September 17, 2026, 30 patients had been enrolled. The enrolment targets are 69 patients by the end of 2026 and 180 patients by the end of 2027.

About SymBio : BCV Business Strategy Based on Three Therapeutic Pillars

Since obtaining the global license for BCV in September 2019, SymBio has advanced collaborative research with world-class institutions to unlock IV BCV's potential across

three strategic therapeutic areas where the Company is currently focusing its development resources: (1) viral infections following hematopoietic stem cell transplantation; (2) solid tumors; and (3) neurodegenerative diseases. By concentrating management resources on these therapeutic areas and actively pursuing global business expansion, SymBio aims to maximize the business value of BCV.