October 23, 2026
SymBio Pharmaceuticals Limited
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Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Completes In-Person Scientific Advice Meeting with the UK MHRA Regarding Conditional Marketing Authorisation (CMA) for Brincidofovir (BCV)

Tokyo, Japan, October 23, 2026 – SymBio Pharmaceuticals Limited ("SymBio" or the "Company") today announced that it completed an in-person scientific meeting with the UK Medicines and Healthcare products Regulatory Agency (MHRA) regarding Conditional Marketing Authorisation (CMA) for intravenous brincidofovir (hereinafter, "IV BCV") for the treatment of adenovirus infection following hematopoietic stem cell transplantation.

At the in-person meeting held on October 20, 2026, at the MHRA headquarters in London, the Company confirmed the data package requirements for IV BCV's CMA application. The session provided clarity on the technical documentation and scope required for the submission.

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 following requirements must be met for Conditional Marketing 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

Phase 3 Clinical Trial for Adenovirus Infection Following Hematopoietic Stem Cell Transplantation

The Company is conducting a global Phase 3 clinical trial in the United States and Europe. As of October 15, 2026, 41 patients had been enrolled, and the Company is on track to complete enrolment of 69 patients by the end of 2026 and 180 patients by the end of 2027 as planned.

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.