

December 14, 2022  
Symbio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

## **Symbio Announces First Patient Dosed in Phase 2 Clinical Trial of Anti-viral Drug Brincidofovir IV in Australia**

TOKYO, Japan, December 14, 2022 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio") today announced First Patient Dosed in its Phase 2 clinical trial of an intravenous formulation of the anti-viral drug brincidofovir ("BCV IV") for treatment of BK virus infection after renal transplantation (the "Study"). BCV IV was administered to the first patient of the Study on December 13, 2022 (Australian Central Time).

The Study will evaluate the safety, tolerability, and efficacy of BCV IV in patients with BK virus infection after renal transplantation, for whom currently there is no effective treatment. The Study will also determine the appropriate dosage and administration for the subsequent clinical trial.

The Company is prioritizing development of BCV IV for BK virus infection in patients after renal transplantation, which can be fatal due to decreased renal function and loss of the transplanted kidney (graft loss), and for which there is significant unmet medical need worldwide due to lack of effective treatment. For this international Study, the Company is also preparing clinical trials in South Korea and Japan.

The Company is also conducting an international Phase 2 clinical trial for BCV IV in patients with adenovirus infection after hematopoietic stem cell transplantation, mainly in the United States, and this Study will evaluate BCV IV in a second indication. Both trials for BK virus infection and adenovirus infection are targeting unmet medical needs, aiming to maximize the benefits to patients and the business value of BCV IV.

Statement from Mr. Fuminori Yoshida, President and Chief Executive Officer of Symbio: "BK virus infection after renal transplantation is an underserved therapeutic area with urgent need for a new treatment as there is currently no effective treatment. The achievement of the first patient dosed in our multinational study is an important first step in Symbio's transformation into a global business."

The Company does not expect the information presented herein to have any material impact on its

financial outlook for the fiscal year ending December 2022.

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**(Note) Renal transplantation and infection**

Renal transplantation is a procedure in which a new kidney is surgically transplanted to restore kidney function for patients suffer from decreased renal function. However, the immune system of the transplant recipient may recognize the transplanted organ as a foreign body and attempt to destroy it (organ rejection). Fever, malaise, irritation of the peritoneum, and pain in the wound may cause damage to the transplanted kidney and may destroy the transplanted organ within approximately a week. Immunosuppressants are used before surgery to reduce organ rejection and protect the transplanted kidney.

Immune recovery after transplantation takes time. However, because immunity is severely compromised, especially immediately after transplantation, the transplant recipient becomes susceptible to various infectious diseases against which it is important to take effective measures early. The prognosis of transplanted kidneys with BK virus nephropathy is poor, and about half are said to move toward loss of the transplanted kidney (graft loss).

There is no established effective therapy for the various infections after renal transplantation, and healthcare providers have long sought an effective and safe treatment.

**About anti-viral drug brincidofovir**

Brincidofovir (BCV) is a lipid conjugate of cidofovir (CDV). CDV is an antiviral drug already approved and marketed in the United States and the European Union, but unapproved in Japan. As BCV exhibits not only higher anti-viral activity, but also a superior characteristics profile in comparison with CDV and other antiviral drugs, BCV is expected to be an effective treatment against a wide spectrum of dsDNA viruses such as herpesviruses such as cytomegalovirus (CMV), adenovirus (AdV), Epstein-Barr virus (EBV), polyomaviruses and papillomavirus. Moreover, BCV is expected to be a highly active antimultiviral agent that can reduce the risk of nephrotoxicity or myelosuppression, which are serious side effects of other antiviral drugs including CDV.

The Company aims to expand its business to become a global specialty pharmaceutical company by 2030. To maximize business value, the Company is currently conducting a global Phase 2 clinical trial mainly in the U.S. for patients with adenovirus infection in immunocompromised conditions including after hematopoietic stem cell transplantation, and initiated a global Phase 2 clinical trial mainly in Australia, Japan, and South Korea for patients with BK virus nephropathy after kidney transplantation.

In addition to its high antiviral activity, BCV is also expected to have anti-tumor effects, and we are currently conducting joint research with the National Cancer Center of Singapore, the University of California, San Francisco, and Brown University in the U.S. to confirm BCV's anti-cancer activity and synergistic effects when combined with its antiviral activity. Furthermore, the Company has initiated a study to evaluate the potential antiviral activity of BCV against EBV in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) in the U.S.

### **About SymBio Pharmaceuticals Limited**

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May 2016, the Company incorporated its wholly-owned subsidiary in the U.S., SymBio Pharma USA, Inc. (Headquarters: Durham, North Carolina, President: Carolyn Yanavich).

The Company's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs.