August 22, 2022
SymBio Pharmaceuticals Limited
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Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio submits clinical trial notification to TGA for Phase 2 clinical trial of anti-viral drug brincidofovir IV for patients with BK virus infection after renal transplantation in Australia

TOKYO, Japan, August 22, 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "the Company") today announced that it has submitted a clinical trial notification (CTN) to the Therapeutic Goods Administration (TGA) of Australian Department of Health to commence an international Phase 2 clinical trial (the "Study") of an intravenous formulation of its anti-viral drug brincidofovir ("BCV IV") for patients with BK virus infection after renal transplantation* in Australia. This submission follows SymBio's CTN submission for the Study in Japan (announced on June 14, 2022).

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 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 clinical trial, the Company is also preparing clinical trials for BK virus infection after renal transplantation in Korea in addition to Japan and Australia.

The Company is also conducting an international Phase II clinical trial for BCV IV in patients with adenovirus infection after hematopoietic stem cell transplantation, mainly in the United States, and the Study is developing the second indication for BCV IV. Both trials for BK virus infection and adenovirus infection are targeting unmet medical needs. The Company strive to expediate the development of BCV IV to deliver it to patients as soon as possible.

The Company does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ended December 31, 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 should be used before surgery to reduce organ rejection and protect the transplanted kidney.

Immune recovery after transplantation takes a long 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 the 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 safety profile in comparison with CDV, 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) and BK virus, papillomavirus. Moreover, BCV is an easy-to-use and novel highly active antimultiviral agent that can reduce the risk of nephrotoxicity, which is a serious side effect of CDV. SymBio entered into an exclusive global license agreement with Chimerix Inc. (Headquarters: Durham, NC, "Chimerix") for brincidofovir (BCV) on September 30, 2019. Under the terms of the agreement, Chimerix grants SymBio exclusive worldwide rights to develop, manufacture, and commercialize BCV in all human indications, excluding the prevention and treatment of orthopox infections (which includes smallpox and monkeypox). To develop global operations, the Company is considering partnerships that will utilize regional characteristics of the target diseases, and striving to maximize the business value of the products and to deliver to patients who need our products as soon as possible. The Company aims to serve the patients not only in Japan but also in Europe and the U.S. market where the market size for organ transplantation is large, and Asia, including the Chinese market.

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: Mr. Fuminori Yoshida).
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.