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

SymBio Announces Global Development of Anti-viral Drug Brincidofovir IV for Treatment of Adenovirus Infection after Hematopoietic Stem Cell Transplantation

TOKYO, Japan, August 5, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that the Company's Board of Directors today approved a global clinical development plan for antiviral drug brincidofovir (BCV) intravenous formulation.

SymBio will prioritize global development of BCV IV targeting adenovirus (AdV) infection occurring after hematopoietic stem cell transplantation, an area with high unmet medical need as there currently exists no effective treatment. Development will primarily be focused in Japan, the U.S., and the EU. The Company will leverage the knowledge of BCV's efficacy and safety gained through the clinical trials to potentially expand target indications to multi-viral infections occurring after hematopoietic stem cell transplantation or viral infections after kidney or other organ transplantation, aiming to expand the market and maximize the business value of BCV.

Since acquiring the exclusive rights to BCV in September 2019, the Company has actively exchanged ideas with experts in the area of infectious diseases, both in and outside Japan, in formulating the global development plan for BCV, including conducting an extensive examination of the scientific and medical aspects of the plan and a business evaluation. Given the extensive antiviral effects of BCV against various dsDNA viruses*, we expect BCV IV to demonstrate efficacy in the treatment and prevention of various viral infections occurring after hematopoietic stem cell transplantation. The Company has determined to prioritize early development for AdV infectious disease after hematopoietic stem cell transplantation which can be fatal without effective treatment and for which there is currently no effective treatment and extremely high medical need worldwide. Based on the findings of the clinical studies of BCV Oral conducted by SymBio's US licensor of BCV, Chimerix Inc. (head office: North Carolina, U.S.), SymBio anticipates that BCV IV will demonstrate efficacy and safety against various infectious diseases such as AdV and cytomegalovirus (CMV).

Statement from Mr. Fuminori Yoshida, President and Chief Executive Officer of SymBio: “Adenovirus infections occurring after hematopoietic stem cell transplantation is an underserved therapeutic area with urgent need for a new drug. Reflecting the views of the members of SymBio’s Global Advisory Board into our strategic priorities and development plan, we will proceed with a global clinical study for pediatric patients with adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, an area with extremely high unmet medical need, and gradually expand target indications to other viral infectious diseases. Transformation into to a global business will be a new challenge for SymBio.”

The Company does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2020.

***dsDNA viruses**

Double-stranded DNA (dsDNA) viruses includes herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as CMV, AdV, HHV-6, BK virus, HSV1/2, VZV, HPV, JCV, and small pox virus.

About Brincidofovir

Brincidofovir (BCV) has a structure in which cidofovir (an antiviral drug already approved and marketed in the U.S. and Europe, but unapproved in Japan; “CDV”) is bound to a lipid chain (hexadecyloxypropyl; “HDP”). It is quickly absorbed into the lipid bilayer membrane and efficiently transfers into cells, and then the bound lipid chain is metabolized and separated from the structure by intracellular phospholipases. This process generates an activator (CDV-PP; CDV diphosphate) that is retained in the cells for a long period of time, dramatically raising the compound’s antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, since HDP conjugation prevents the accumulation of the compound in renal tubular epithelial cells through organic anion transporter 1 (OAT1) and CDV is released at low levels in the bloodstream.

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 smallpox. For further information, please see the SymBio’s press release dated October 1, 2019, https://www.symbiopharma.com/news/20191001.pdf

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Its two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

BCV is an antiviral drug candidate in development as a medical countermeasure for smallpox. For further information, please visit the Chimerix website, www.chimerix.com.

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., called SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, 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.