June 7, 2021
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Chimerix receives U.S. Food and Drug Administration approval for brincidofovir for the treatment of smallpox

TOKYO, Japan, June 7, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that Chimerix Inc. (Headquarters: Durham, NC, "Chimerix") announced on June 4, 2021 (US EST) that the U.S. Food and Drug Administration (FDA) has granted brincidofovir (BCV) tablets and oral suspension approval for the treatment of smallpox. It is approved for adult and pediatric patients, including neonates.

Chimerix developed the BCV oral formulations as a medical countermeasure for smallpox under an ongoing collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. Chimerix looks forward to advancing its discussions with BARDA toward a procurement contract to support national preparedness. For further information, please see Chimerix's website: https://ir.chimerix.com/press-releases

SymBio, pursuant to a license agreement with Chimerix entered into on September 30, 2019, obtained the 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). SymBio is preparing to initiate a global study of BCV targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation.

The Company does not expect the information presented to have a material impact on its financial outlook for the fiscal year ending December 31, 2021.

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About Smallpox

Smallpox is a highly contagious disease caused by the variola virus. Historically, smallpox was one of the deadliest diseases in history with a case fatality rate of approximately 30%. Despite successful eradication of smallpox in the 1970s, there is considerable concern that variola virus could reappear, either through accidental release or as a weapon of bioterrorism. According to the U.S. Centers for Disease Control and Prevention (CDC), variola virus is ranked in the highest risk category for bioterrorism agents (Category A) due to its ease of transmission, high mortality rate, and potential to cause public panic and social disruption.

About Anti-viral Drug Brincidofovir

Brincidofovir (BCV) is a lipid-conjugate of cidofovir (an antiviral drug already approved and marketed in the U.S. and Europe, but unapproved in Japan; "CDV"). In addition to its antiviral effect, BCV was intended to be designed to have improved safety profile as compared to CDV. Therefore, BCV is expected to be an effective treatment for a wide range of DNA viruses (e.g., herpesviruses such as cytomegalovirus (CMV), adenovirus (AdV), BK virus, papillomavirus, etc.).
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 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).
SymBio aims to further globalize business, establish an integrated system for the supply of high-quality pharmaceutical products, and grow as a specialty pharmaceutical company through the exclusive global license for BCV. 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.

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 three most advanced clinical-stage development programs are BCV, ONC201 and DSTAT. BCV is an antiviral drug candidate developed as a potential medical countermeasure for smallpox and is currently under review for regulatory approval in the United States. ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and a confirmatory response rate assessment is expected later this year. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia. 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.