December 8, 2020
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Chimerix Announces FDA Acceptance of New Drug Application for Brincidofovir as a Medical Countermeasure for Smallpox

FDA Grants Priority Review and Sets PDUFA Date for April 7, 2021

TOKYO, Japan, December 8, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that Chimerix Inc. (Headquarters: Durham, NC, "Chimerix") announced on December 7, 2020 (US EST) that the U.S. Food and Drug Administration (FDA) accepted the filing of a New Drug Application (NDA) for antiviral drug brincidofovir (BCV) as a medical countermeasure for smallpox. The FDA granted Priority Review and set an action date of April 7, 2021 under the Prescription Drug User Fee Act (PDUFA). 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), and SymBio is preparing to initiate a global study of BCV targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation.

Chimerix is developing BCV as a potential medical countermeasure for smallpox under an ongoing collaboration and funding provided by 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.

For more information, please see Chimerix's website:
https://ir.chimerix.com/press-releases

Mr. Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated: "The completion of the NDA filing by Chimerix for BCV to the FDA on a rolling submission basis is a very important milestone for us as we continue to develop BCV globally."

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 and is currently under review for regulatory approval in the United States. For further information, please visit the Chimerix website, www.chimerix.com.

About the Global License Agreement for Brincidofovir

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

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.