November 24, 2021
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio receives approval of shelf-life extension for TREAKISYM® ready-to-dilute (RTD) liquid formulation

TOKYO, Japan, November 24, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio" or the "Company") today announced that it has obtained approval of a partial change to its Marketing Authorization for TREAKISYM® ready-to-dilute liquid formulation ("RTD") to extend the shelf life of RTD to 30 months based on the results of long-term stability testing.

Under the license agreement entered into between SymBio and Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA) in September 2017, SymBio obtained the exclusive rights to develop and commercialize the patent-protected liquid formulation of bendamustine hydrochloride (bendamustine HCl) in Japan, enabling SymBio to extend the product life of TREAKISYM® through 2031. RTD provides significant benefits to healthcare professionals as it requires less time to prepare than the freeze-dried formulation.

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

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About TREAKISYM®

TREAKISYM® (non-proprietary name: bendamustine hydrochloride), a cytocide anti-cancer drug first used in Germany in the 1970s, is now widely used in more than 50 countries with indications for low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia.

- TREAKISYM® Intravenous Infusion, freeze-dried (FD) formulation, was approved in October 2010 for manufacturing and marketing for the indication of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan.
- TREAKISYM® was approved for the additional indication of chronic lymphocytic leukemia in Japan in August 2016.
- TREAKISYM® was approved for the additional indications of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December 2016.
- TREAKISYM® ready-to-dilute (RTD) liquid formulation was approved in Japan in September 2020 for all the above indications.
- TREAKISYM® FD and RTD were approved for the additional indication of relapsed or refractory DLBCL in March 2021 and April 2021, respectively.

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, SymBio incorporated its wholly-owned subsidiary in the U.S., SymBio Pharma USA, Inc. (Headquarters: Durham, North Carolina, President: Mr. Fuminori Yoshida). SymBio'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.