

June 18, 2018  
Symbio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

## **Eagle Announces U.S. Court Decision Granting Orphan Drug Exclusivity for Bendamustine Hydrochloride Injection in the U.S.**

TOKYO, Japan, June 18, 2018 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio,") announced today that its U.S. partner, Eagle Pharmaceuticals, Inc. (Headquarters: Woodcliff Lake, NJ, "Eagle") announced on June 11, 2018 that the U.S. District Court for the District of Columbia has issued a decision requiring the FDA to grant seven years of orphan drug exclusivity in the U.S., for BENDEKA® (bendamustine hydrochloride injection). Under the terms of the license agreement concluded with Eagle in September 2017 <sup>(\*)</sup>, Symbio has an exclusive license to develop, market and sell Eagle's bendamustine hydrochloride ready-to-dilute (RTD) and rapid infusion (RI) injection products in Japan.

Currently, BENDEKA® has acquired 97% of the U.S. bendamustine market share. This decision will extend Eagle's market exclusivity for its bendamustine hydrochloride injection in the U.S. to December 2022. In addition, thirteen U.S. patents provide patent protection extending through 2033.

For Eagle's full press release, please visit the company's website.

<http://investor.eagleus.com/>

(\*)Please refer to Symbio's IR News "Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to Symbio Pharmaceuticals Limited" issued on September 21, 2017 for the conclusion of a licensing agreement with Eagle.

[http://www.symbiopharma.com/news\\_e/20170921\\_1e.pdf](http://www.symbiopharma.com/news_e/20170921_1e.pdf)

### **About Eagle Pharmaceuticals, Inc.**

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle's strategy is to utilize the FDA's 505(b)(2) regulatory pathway. Additional information is available on the Company's website at [www.eagleus.com](http://www.eagleus.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., 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 with main therapeutic focus in oncology, hematology and pain management.