

# Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited

September 20, 2017

- Begins Process to Maximize Value of Eagle's Product Portfolio Worldwide -
- \$12.5 Million Upfront Payment Plus Future Potential Milestones and Royalty Payments -

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or "the Company") and SymBio Pharmaceuticals Limited ("SymBio") (Tokyo Stock Exchange/JASDAQ 4582) today announced that the Company has licensed to SymBio rights under Eagle's intellectual property to develop, market and sell Eagle's bendamustine hydrochloride ("bendamustine HCl") ready-to-dilute ("RTD") and rapid infusion ("Rl") injection products in Japan.

SymBio will be responsible for securing regulatory approval of the RTD and RI injection products using the licensed technology in Japan with a target for approval of a product in 2020. SymBio currently markets TREAKISYM® in Japan, a lyophilized powder formulation of bendamustine HCl indicated for chronic lymphocytic leukemia ("CLL"); relapsed or refractory low-grade Hodgkin's lymphoma ("NHL"); mantle cell lymphoma ("MCL"); and as a first line treatment of low-grade NHL and MCL. According to SymBio, 12-month sales ended June 30, 2017 in Japan for TREAKISYM were \$52 million, due to the approval of first line treatment for NHL and MCL in December 2016. SymBio has estimated that sales of TREAKISYM are estimated to grow to \$90 million in 2018.

A 50 ml RI or rapid infusion presentation of bendamustine hydrochloride injection is currently marketed in the U.S. by Teva Pharmaceutical Industries, Ltd. ("Teva") as BENDEKA® (bendamustine HCI) Injection. BENDEKA currently has a 97% market share of the bendamustine market, and Teva has forecasted the North American market for bendamustine to be approximately \$600 - \$660 million in sales in 2017. BENDEKA's low volume infusion and short infusion time represents an important benefit to both patients and healthcare providers.

Pursuant to the terms of the license with SymBio, Eagle will receive a \$12.5 million upfront milestone payment, and may be entitled to additional milestone payments upon approval and the achievement of cumulative sales thresholds. The Company will also receive royalties on future net sales of the licensed bendamustine products.

"This is an important example of the value of the Eagle portfolio to patients worldwide and a first step in expanding outside the U.S. for our differentiated products. We look forward to SymBio's future approval and successful commercialization of bendamustine HCI in Japan," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Mr. Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated, "In-licensing Eagle's ready-to-dilute and rapid infusion injection products will enable SymBio to extend the product life and continue to maximize the value of TREAKISYM over the product life while bringing significant benefits to patients and healthcare providers in Japan."

## 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 <a href="https://www.eagleus.com">www.eagleus.com</a>.

# **Forward-Looking Statements**

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended and other securities laws. Forward-looking statements are statements that are not historical facts. Words such as "will," "may," "intends," "anticipate(s)," "plan," "enables," "potentially," "forecasted", "entitles," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events, including, but not limited to: forecasted sales of \$90 million in 2018; forecasted sales of Bendeka in 2018; SymBio's plans to secure regulatory approval of bendamustine HCl in a 500ml ready to infuse and/or a 50 ml rapid infusion presentation; SymBio's target to market the smaller volume product in Japan in 2020; the success of Eagle's commercial relationship with SymBio and the companies' ability to successfully work together; payments due to Eagle under the license with SymBio, including milestone and royalty payments; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year December 2016, and its other filings with the U.S. Securities and Exchange Commission. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks include, but are not limited to: whether SymBio will be successful at commercializing the licensed products; whether Eagle and SymBio will perform their respective obligations under the license agreement; inaccurate sales forecasts and estimates; the ability of SymBio to obtain regulatory approval for its bendamustine products; and other risks described in Eagle's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

#### **About TREAKISYM®**

TREAKISYM® (non-proprietary name: bendamustine HCl), a cytocide anti-cancer drug, 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 100 mg 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® Intravenous Infusion 25 mg, a standard low-dose product, was approved for manufacturing and marketing in Japan in September, 2016.

TREAKISYM® was approved for the additional indication of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December, 2016.

TREAKISYM® has been marketed in Japan through Eisai Co., Ltd. since December, 2010.

### **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., called SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, 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 with main therapeutic focus in oncology, hematology and pain management.

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