Eagle Pharmaceuticals' Japanese Licensing Partner SymBio Announces Completion of Clinical Trial Enrollment for TREAKISYM® Rapid Infusion Liquid Bendamustine Formulation

March 30, 2020

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (NASDAQ: EGRX) today announced that its marketing partner SymBio Pharmaceuticals Limited ("SymBio") has completed patient enrollment in a clinical trial for TREAKISYM rapid infusion ("RI"), a liquid bendamustine injection with a 10-minute administration time, in Japan. The study's primary objective is to confirm the safety of the RI product. SymBio expects to obtain regulatory approval in the second half of 2022.

SymBio intends to submit a New Drug Application ("NDA") for the RI product for all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). As previously disclosed, SymBio filed an NDA for its TREAKISYM ready-to-dilute ("RTD") product in October 2019.

In September 2017, Eagle licensed to SymBio intellectual property necessary to develop, market and sell RTD and RI formulations of TREAKISYM in Japan. As part of the agreement, SymBio assumed responsibility for securing regulatory approval of the TREAKISYM RTD and RI injection products using the licensed technology in Japan.

Pursuant to the terms of the license with SymBio, Eagle received a $12.5 million upfront milestone payment in 2017, and is entitled to additional milestone payments, including $5 million upon approval of an NDA for either TREAKISYM RTD or RI, and other amounts upon achievement of cumulative sales thresholds. Eagle will also receive royalties on future net sales of the licensed bendamustine products.

According to SymBio, sales in Japan for TREAKISYM were $78 million in 2019.

"SymBio continues to make excellent progress in advancing TREAKISYM RTD and RI for approval in Japan as evidenced by the completion of enrollment of the safety study for the RI product. With anticipated future approvals for both the TREAKISYM RTD and RI products, we look forward to SymBio's successful commercialization in Japan, allowing patients to benefit from these products' key advantages," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

About Eagle Pharmaceuticals, Inc.

Eagle is a pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Additional information is available on the Company's website at www.eagleus.com.

Eagle's 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 "likely," "will," "may," "can," "could be," "believe," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: confirmation of the safety of TREAKISYM RTD and RI products, approval by the Japanese Health Regulatory Agency of RTD and RI versions of TREAKISYM, the future commercial success of such products; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2019, 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. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does 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.

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