Eagle Pharmaceuticals' Japanese Licensing Partner SymBio Announces its Submission of a New Drug Application for TREAKISYM® Ready-To-Dilute Formulation

October 7, 2019

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 submitted a New Drug Application ("NDA") for TREAKISYM ready-to-dilute ("RTD") liquid formulation in Japan. The NDA covers all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). SymBio expects to launch the TREAKISYM RTD product in the first quarter of 2021, after obtaining marketing authorization.

In September 2017, Eagle licensed to SymBio intellectual property necessary to develop, market and sell RTD and rapid infusion ("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 the NDA, 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 2018 and $77 million through June 30, 2019.

"We are pleased that SymBio has made great progress in advancing TREAKISYM toward regulatory approval in Japan. We look forward to SymBio's future approval and successful commercialization of bendamustine HCI in Japan, enabling patients there to benefit from TREAKISYM's key advantages," stated Scott Tarriff, Chief Executive Officer.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty 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.

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 and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," 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: approval by the Japanese Health Regulatory Agency of RTD and RI versions of TREAKISYM and the future commercial success of such products. 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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