Eagle Pharmaceuticals Announces Filing of TREAKISYM (bendamustine) Rapid Infusion (“RI”) Liquid Formulation in Japan

May 10, 2021

- Eagle expects approximately $20-$25 million from combined royalty and milestone revenue in 2022 for TREAKISYM (bendamustine) Ready-to-Dilute (“RTD”) and Rapid Infusion (“RI”) formulations -

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (“Eagle” or the “Company”) (NASDAQ: EGRX) today announced that TREAKISYM RI (50ml) liquid formulation has been filed with the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan.

The application is based on the results of clinical studies investigating the safety and pharmacokinetics of TREAKISYMRTD administered by 10-minute intravenous infusion.

“We are pleased that the RI application has been submitted ahead of schedule, which will enable patients and providers alike to reap the benefits of this formulation. We believe we can get close to peak income of $20-$25 million as early as next year from the RTD and RI products. This is an important extension of the bendamustine franchise, and we value the relationship with Symbio,” stated Scott Tarriff, Chief Executive Officer.

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

TREAKISYM RI has the advantage of reducing infusion time to 10 minutes (from the current 60 minutes), eliminating the need for manual reconstitution and significantly reducing preparation time, benefitting both patients and healthcare providers.

About Eagle Pharmaceuticals, Inc.
Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients’ lives. Eagle’s commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle’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: the timing of regulatory approvals for the TREAKISYM RI formulation, if ever; the future commercial success of TREAKISYM RTD and, if approved, TREAKISYM RI, including anticipated royalty and milestone revenue and potential market opportunity; expectations regarding the potential benefits of TREAKISYM RTD and TREAKISYM RI for patients and healthcare providers; and the Company’s ability to successfully collaborate with Symbio with respect to the commercialization of TREAKISYM RTD and RI formulations. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company'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 and uncertainties include, but are not limited to: risks that the Company's or its partners’ business, financial condition and results of operations will be impacted by the spread of COVID-19 in the geographies where such parties operate; whether the Company will incur unforeseen expenses or liabilities or other market factors in connection with COVID-19; the success of the Company's collaborations with its strategic partners; successful compliance with governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; and those risks and uncertainties identified in the “Risk Factors” sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2021, as updated by the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, which the Company expects to file with the SEC on May 10, 2021, and its other subsequent filings with the SEC. 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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