Eagle Pharmaceuticals Announces TREAKISYM (bendamustine) Ready-to-Dilute (“RTD”) Formulation, in Combination with Rituximab for Treatment of Relapsed or Refractory Diffuse Large B-cell Lymphoma Receives PMDA Approval in Japan

April 30, 2021

-Eagle believes new indication could allow for a significant expansion of the overall market opportunity-

-RTD and Rapid Infusion (“RI”) formulations anticipated to generate approximately $25 million of combined royalty and milestone revenue at peak-

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (“Eagle” or the “Company”) (NASDAQ: EGRX) today announced that TREAKISYM ready-to-dilute (“RTD”) (bendamustine hydrochloride 120 mg/m ^{2}) liquid formulation has been approved for a new indication in combination with rituximab (“BR therapy”) as treatment for relapsed or refractory diffuse large B-cell lymphoma (“r/r DLBCL”) by the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan.

“This latest approval is another meaningful extension of our bendamustine franchise. We believe this expanded label will significantly increase the market opportunity for TREAKISYM in Japan. Based on this additional indication, as well as the anticipated approval of the ten-minute RI liquid formulation, we are reiterating our belief that the combined royalty and milestones revenue from these products will generate $25 million at peak,” 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.

SymBio received approval for the TREAKISYM RTD (250 ml) liquid formulation in September 2020 and is currently conducting a clinical safety trial for the ten-minute RI (50 ml) liquid formulation, for which it plans to seek approval in the second half of 2022.

Key benefits to patients and healthcare providers of these products include eliminating the need for manual reconstitution and significantly reducing preparation time as compared to the lyophilized formulation.

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 ability to advance TREAKISYM RTD in combination with BR therapy as a treatment for r/r/ DLBCL; the future commercial success of TREAKISYM RTD and TREAKISYM RI, including anticipated royalty and milestone revenue and potential market opportunity; the timing of regulatory approvals for the TREAKISYM RI formulation, if ever; 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 on March 5, 2021 and its other subsequent filings with the 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 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793

E: lwilson@insiteconv.com

Source: Eagle Pharmaceuticals, Inc.