Eagle Pharmaceuticals Announces FDA Maintains Prioritization of ANDA for Vasopressin

June 24, 2021

-- Assigned GDUFA date of December 15, 2021, and expects commercial launch prior to year-end --

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Food and Drug and Administration ("FDA") has maintained Priority Review for the Company's Abbreviated New Drug Application ("ANDA") for vasopressin. The Company's response to the CRL was submitted on June 15, 2021. The FDA has assigned a GDUFA date of December 15, 2021, and the Company expects a commercial launch prior to year-end.

"Vasopressin is an important program for us, and in light of the Priority Review, as well as its being flagged as a COVID priority, we continue to believe that we can bring this product to market this year. The trial is set to commence on July 7, and we look forward to providing updates in the near future," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Eagle is first to file an ANDA referencing Vasostrict, which had total U.S. sales of $786 million in 2020.

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 statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. 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 concerning the Company's ability to address the questions raised in the CRL for its ANDA for vasopressin and to communicate with FDA regarding the same; the Company's ability to obtain and maintain regulatory approval of its products and product candidates, including vasopressin; the timing, progress and results of the Company's clinical trials, including potential timing of commercial launch of vasopressin; and the ability of the Company's product candidates, including vasopressin, to deliver value to stockholders. 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: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; delay in or failure to obtain regulatory approval of the Company's product candidates and successful compliance with FDA and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates; whether the Company can successfully market and commercialize its product candidates; the outcome of litigation involving any of its products or that may have an impact on any of its products; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" section 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, filed with the SEC on May 10, 2021, and its other subsequent filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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