Eagle Pharmaceuticals Receives FDA Approval for Vasopressin

December 15, 2021

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

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Food and Drug Administration ("FDA") has approved the Company's abbreviated new drug application ("ANDA") for vasopressin. This approval follows the recent U.S. District Court for the District of Delaware decision holding that Eagle's proposed vasopressin product does not infringe any of the patents Par Pharmaceutical, Inc. et al. asserted against the Company.

"We expect vasopressin to be a significant addition to our hospital and critical care portfolio, and we are delighted to now have final FDA approval for our A-rated, therapeutic equivalent product. We also anticipate 180-day marketing exclusivity. This is an important product for us, and a much-needed generic alternative to Vasostrict® for providers and patients. We are implementing our launch plans to bring vasopressin to market," stated Scott Tarriff, President and Chief Executive Officer of Eagle.

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, the Company's ability to obtain and maintain regulatory approval of its products and product candidates, including the ANDA for vasopressin; whether or not Par Pharmaceutical, Inc. will appeal the court's ruling or the outcome of any such appeal; the timing and progress of the Company's potential launch of vasopressin; the ability of the Company to successfully commercialize vasopressin; the ability of vasopressin to benefit providers and patients as an alternative to Vasostrict; the period of marketing exclusivity for 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, European Medicines Agency and other governmental regulations applicable to product approvals; 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 Reports on Form 10-Q for the quarters ended March 31, 2021, June 30, 2021 and September 30, 2021 filed with the SEC on May 10, 2021, August 9, 2021 and November 9, 2021, respectively, 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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