Eagle Pharmaceuticals Announces Commercial Availability of Vasopressin

January 18, 2022

-- Shipment of vasopressin, a generic alternative to Vasostrict®,commences today, with 180 days of marketing exclusivity --

-- Product launch expected to drive significant revenue growth in 2022 --

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced the commercial availability of its recently approved product, vasopressin, an A-rated generic alternative to Vasostrict®, with 180 days of marketing exclusivity. U.S. sales of Vasostrict totaled $890 million for the LTM ended September 30, 2021.[1]

On December 15, 2021, the U.S. Food and Drug Administration ("FDA") approved Eagle's abbreviated new drug application ("ANDA") for vasopressin, a product that is indicated for use to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

"The Eagle team has worked very hard to advance vasopressin for patients in need. We believe our highly experienced hospital and critical care sales force gives us a significant strategic advantage as we make inroads into this important market, and we have already entered into contracts with customers. With the 180-day period of marketing exclusivity, we believe we will deliver value to our shareholders and vasopressin will contribute meaningfully to Eagle's growth," stated Scott Tarriff, President and Chief Executive Officer of Eagle.

Eagle was first-to-file an ANDA referencing Par Pharmaceutical, Inc.'s Vasostrict for the 20 units per ml presentation. On August 31, 2021, the U.S. District Court for the District of Delaware held that Eagle's proposed vasopressin product does not infringe any of the patents Par asserted against Eagle. Par's appeal of the District Court's ruling remains pending, and Eagle will continue to vigorously defend against such appeal.

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; the plans and success of the Company's vasopressin launch, including with respect to strategic advantages of the Company; the ability of the Company to successfully commercialize its product candidates, including vasopressin, and potential earnings and resulting growth from such products; the ability of vasopressin to benefit providers and patients as an alternative to Vasostrict; the period of marketing exclusivity for vasopressin; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the ability of the Company's executive team to execute on the Company's strategy and to utilize its cash and other assets to deliver shareholder value; and the ability of the Company's product candidates 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; whether the Company will incur unforeseen expenses or liabilities or other market factors; 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; whether the Company will successfully implement its development plan for its product candidates, including its fulvestrant product; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the outcome of litigation involving any of its products or that may have an impact on any of its products; successful compliance with the FDA and other 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 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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