Federal Circuit Rules in Favor of Eagle Pharmaceuticals in Vasopressin Litigation

August 18, 2022

WOODCLIFF LAKE, N.J., Aug. 18, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) today announced that the U.S. Court of Appeals for the Federal Circuit affirmed the U.S. District Court for the District of Delaware’s decision that Eagle’s vasopressin product does not infringe on any of the patents asserted by Par Pharmaceutical, Inc. (“Par”).

Par previously sued Eagle in 2018, alleging infringement of several of its patents and a trial was held in July 2021. The District Court held that Eagle did not infringe on any of Par’s patents, and Par appealed. Oral arguments were held before the Federal Circuit in July 2022. Today, the Federal Circuit issued its decision rejecting Par’s arguments and affirming the District Court’s finding of non-infringement.

Eagle was the first to file an Abbreviated New Drug Application (“ANDA”) referencing Vasostrict ®. On December 15, 2021, the U.S. Food and Drug Administration (“FDA”) approved Eagle’s 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. Eagle commenced marketing its product in January 2022.

Kirkland & Ellis LLP is counsel for 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 vasopressin, PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and BYFAVO® and BARHEMSYS® through its wholly owned subsidiary Acacia Pharma Inc. Eagle’s 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; the outcome of any potential appeal of the ruling in the vasopressin matter; the timing and progress of the Company’s 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” sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which the Company expects to file with the SEC on August 9, 2022. Readers are cautioned not to place undue reliance on these forward-looking statements. 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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