



Eagle Pharmaceuticals Provides Update on Bendamustine Intellectual Property Portfolio

January 18, 2024

WOODCLIFF LAKE, N.J., Jan. 18, 2024 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today provided an update on its bendamustine intellectual property portfolio.

On January 16, 2024, the United States Court of Appeals for the Federal Circuit affirmed the previously announced decision by the United States District Court for the District of Delaware finding that the 505(b)(2) drug applications referencing BELRAPZO[®] filed by Slayback Pharma Limited Liability Company ("Slayback")¹ and Apotex Inc. and Apotex Corp. ("Apotex") did not infringe Eagle's previously issued '483 patent. Slayback, Apotex, and Baxter Healthcare Corporation ("Baxter") launched their respective products in December of 2022.

Eagle is also announcing that the U.S. Patent and Trademark Office has granted U.S. Patent Nos. 11844783 (the "'783 patent") and 11872214 (the "'214 patent") covering Eagle's innovative bendamustine liquid formulations. The patents are listed in the Orange Book for both BENDEKA[®] and BELRAPZO.

On January 17, 2024, Eagle filed lawsuits asserting that 505(b)(2) products referencing BELRAPZO marketed by Slayback, Apotex, and Baxter each infringe one or more claims of the newly issued '783 and '214 patents and requesting damages for any infringing sales of the parties' respective accused products. Eagle intends to seek lost profits and other damages from any and all infringing sales of the defendants' bendamustine products, as well as injunctive relief requiring the defendants to cease all sales of their infringing products until the expiration of the patents in 2031.

"We are pleased to maximize our intellectual property for the bendamustine franchise and will continue to take appropriate steps to enforce our rights related to the newly issued patents," stated Michael Graves, Interim Principal Executive Officer and Interim Executive Chairman of the Board of Eagle.

Eagle cannot predict the timing or ultimate outcome of the litigation described above or the impact of this litigation on its business. In addition, Eagle made the allegations described above based only on information currently known to it. These allegations have not been fully litigated and the information and assumptions underlying these allegations may change after the date of hereof. Moreover, notwithstanding Eagle's allegations and its views on the merits of this litigation, litigation is inherently uncertain and there can be no guarantee that the court will agree with Eagle's allegations or interpretation of applicable regulations or laws, or that Eagle will otherwise prevail in this litigation. Accordingly, the allegations described above are not intended to be statements of fact to be relied upon by Eagle's shareholders or potential investors.

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 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, and the company is focused on developing medicines with the potential to become part of the personalized medicine paradigm in cancer care. 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," "could," "may," "intend," "remain," "potential," "prepare," "expected," "believe," "plan," "seek," "continue," "estimate," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements with respect to: the Company's expectations relating to BENDEKA and BELRAPZO, including related litigation, including the Company's allegations with respect to infringement of its '783 and '214 patents and potential damages related thereto and the Company's expectations with respect to enforcement of its intellectual property rights; the issuance and listing of patents for BENDEKA and BELRAPZO in the FDA's Orange Book and related consequences therefrom; the Company's ability to develop innovative medicines that result in meaningful improvements in patients' lives; the ability of the Company's products and product candidates to address underserved therapeutic areas across multiple disease states; and the Company's ability to develop medicines with the potential to become part of the personalized medicine paradigm in cancer care. All 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 completion of the review and preparation of the Company's financial statements and internal control over financial reporting and disclosure controls and procedures and the timing thereof; the discovery of additional information; further delays in the Company's financial reporting, including as a result of unanticipated factors; the Company's ability to comply with its obligations under its credit agreement; the possibility that the Company will be unable to regain compliance with, or thereafter continue to comply with, the Nasdaq Listing Rules, or experience violations of additional Nasdaq Listing Rules; the possibility that the Nasdaq may delist the Company's securities; the Company's ability to remediate material weaknesses in its internal control over financial reporting; the Company's ability to recruit and hire a new Chief Executive Officer; the impacts of the post- COVID-19 environment and geopolitical factors such as the conflicts between Russia and Ukraine and Gaza and Israel; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates and successful compliance with Federal Drug Administration, European Medicines Agency and other governmental regulations applicable to product approvals; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; whether the Company can successfully market and commercialize its products; the success of the Company's relationships with its partners; the outcome of litigation; 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 competition from generic entrants into the market; unexpected safety or efficacy data observed during clinical trials; clinical trial site activation or enrollment rates that are lower than expected; the risks inherent in drug development and in conducting clinical trials; risks inherent in estimates or judgments relating to the Company's critical accounting policies, or any of the Company's estimates or projections, which may prove to be inaccurate; unanticipated factors in addition to the foregoing that may impact the Company's financial and business projections and guidance and may cause the Company's actual results and outcomes to materially differ from

its estimates, projections and guidance; 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, 2022, filed with the Securities and Exchange Commission (the “SEC”) on March 23, 2023, the Company’s Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, and for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023, and its other subsequent filings with the SEC. 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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¹ On September 27, 2023, Azurity Pharmaceuticals acquired Slayback Pharma.