

Eagle Pharmaceuticals Granted Additional Patent for Bendamustine Franchise

August 31, 2021

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Patent and Trademark Office has granted the Company U.S. Patent No. 11,103,483, entitled "Formulations of Bendamustine." Eagle is submitting the '483 patent for listing in the U.S. Food and Drug Administration's Orange Book for both BENDEKA [®] and BELRAPZO[®].

Eagle had asserted several Orange Book-listed patents against Slayback Pharma LLC, Apotex Inc. et al, Mylan Laboratories Limited, and Fresenius Kabi USA, LLC, related to their respective abbreviated new drug applications referencing BENDEKA. On July 6, 2020, the District Court for the District of Delaware had held these asserted patents both valid and infringed. Apotex, Mylan, and Fresenius appealed this ruling. Previous to the appellate hearing, Eagle settled the Fresenius litigation. On August 13, 2021, the United States Court of Appeals for the Federal Circuit affirmed that the asserted patents were both valid and infringed. Both the asserted patents and the '483 patent expire in 2031.

"We are pleased that this appellate decision, as well as the newly issued patent, continue to strengthen Eagle's intellectual property rights for both BENDEKA and BELRAPZO," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

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 submission of U.S. Patent No. 11,103,483 for listing in the U.S. Food and Drug Administration's Orange Book for both BENDEKA and BELRAPZO; and statements regarding the strength of the Company's intellectual property rights for BENDEKA and BELRAPZO. 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, EMA 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 and June 30, 2021, filed with the SEC on May 10, 2021 and August 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: |wilson@insitecony.com

Source: Eagle Pharmaceuticals, Inc.