



Eagle Pharmaceuticals Reaches Settlement Agreement with Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. Related to BENDEKA® (bendamustine hydrochloride)

April 5, 2023

WOODCLIFF LAKE, N.J., April 05, 2023 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has reached a settlement agreement with Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"). Eagle had asserted its Orange Book-listed patents against Dr. Reddy's related to its new drug application referencing BENDEKA®. Under the settlement agreement, Dr. Reddy's has the right to market its product beginning November 17, 2027, or earlier based on certain circumstances. The settlement agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The settlement with Dr. Reddy's follows Eagle's previously announced settlements with Hospira, Inc. ("Hospira") and Accord Healthcare, Inc. ("Accord") related to their new drug applications referencing BENDEKA®.

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," "opportunity," "estimate," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the resolution of patent litigation and all related settlement terms, including dates of market entry and the potential for earlier market entry under certain circumstances and submission of settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice for review; the strength of the Company's intellectual property rights for BENDEKA; and the expected expansion, defense and enforcement of intellectual property rights. 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. 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Such risks and uncertainties include, but are not limited to: the risk that the anticipated benefits of the Company's acquisition of Acacia are not realized; the ability of Enalare to achieve milestones and deliverables under the BARDA agreement and achieve successful results in the development of ENA-001 and the Company's ability to exercise its option to acquire the remaining outstanding share capital of Enalare; the impacts of the COVID-19 pandemic and geopolitical events such as the conflict in Ukraine, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy, and the overall impact of the COVID-19 pandemic or other events on the Company's business, financial condition and results of operations; macroeconomic conditions, including rising inflation and uncertain credit and financial markets; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of our 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 and geopolitical events, 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 the early stages of drug development and in conducting clinical trials; and any 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 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, 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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