Eagle Pharmaceuticals Announces Submission of Investigational New Drug Application to U.S. Food and Drug Administration for CAL02, a Novel First-in-Class Broad-Spectrum Anti-Virulence Agent for the Treatment of Severe Community-Acquired Bacterial Pneumonia

October 12, 2022

-- Company plans to commence an adequately powered Phase 2 study with approximately 276 patients with severe community-acquired pneumonia at 120 sites worldwide with patient enrollment expected as early as the beginning of 2023 --

-- Interim results expected approximately one year after patient enrollment begins --

-- CAL02 is being developed as an add-on to the clinically indicated antibiotic treatment and potentially offers unique therapeutic benefits to critically ill patients, including immediate decrease in inflammatory biomarkers, shorter duration of critical care management such as mechanical ventilation, and ultimately a reduced mortality risk --

WOODCLIFF LAKE, N.J., Oct. 12, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") announced today that it has submitted an investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia ("SCABP").

The IND filing includes a protocol for an adequately powered global Phase 2 study to evaluate the efficacy and safety of CAL02 when added to standard of care therapy in patients with SCABP. The design, entry criteria, and endpoints for the proposed Phase 2 study have been discussed with the FDA in a pre-IND meeting held on September 19, 2022. The Phase 2 study plans to enroll approximately 276 patients with SCABP at 120 sites worldwide. Patient enrollment is expected as early as the beginning of 2023.

"CAL02 is a very interesting agent with a unique mechanism of action. The IND filing is an important regulatory milestone as it paves the way for us to begin what we believe will be a very robust Phase 2 proof-of-concept study. CAL02 has the potential to shift the treatment paradigm for patients with severe community-acquired pneumonia, a leading cause of death worldwide. Intended as an add-on to clinically indicated antibiotic treatment, CAL02 acts as a neutralizer of bacterial virulence factors, considered responsible for complications associated with severe pneumonia, and we believe it has the potential to shorten the need for costly critical care management, overall hospital stays, and improve patient outcomes," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "In medical literature, CAL02 has been referred to as a medical breakthrough, and we are excited for the prospect of adding this important therapeutic to our acute care product portfolio," concluded Tarriff.

"Severe community-acquired bacterial pneumonia is a challenging disease to treat and remains among the leading causes of death in infectious diseases worldwide.[1] Historically, around one quarter[2] of patients diagnosed with SCABP become critically ill, and the potential to use CAL02 in combination with traditional antibacterial drugs would provide physicians with a powerful tool to manage SCABP in critically ill patients and improve outcomes," stated Dr. Andre Kalil, MD, MPH, University of Nebraska Medical Center.

Eagle anticipates filing for ten years of regulatory exclusivity, including five years as a new chemical entity and five years as a qualified infectious disease product ("QIDP") under the Generating Antibiotic Incentives Now ("GAIN") Act. Eagle believes that CAL02 could be eligible for fast track and breakthrough therapy designations. In addition, Eagle believes a CAL02 new drug application for the treatment of SCABP may qualify for priority review. The Company expects to strengthen the patent portfolio for this asset.

In August 2021, Eagle entered into a worldwide licensing agreement with Combioxin SA, a clinical-stage biotechnology company based in Epalinges, Switzerland, for the commercial rights to CAL02. As previously announced, the Company expects to invest $35 million to achieve interim results from the Phase 2 study expected in late 2023/early 2024.

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 expected investment to achieve interim results from the planned Phase 2 study with respect to CAL02 for the potential treatment of SCABP; the potential of CAL02 to be a medical breakthrough and offer unique therapeutic benefits to critically ill patients, including immediate decrease in inflammatory biomarkers, shorter duration of critical care management such as mechanical ventilation, and ultimately a reduced mortality risk; statements with respect to the design and timing of the planned Phase 2 study, enrollment and results therefrom; the potential of CAL02 to shift the treatment paradigm for patients with SCABP; the potential of CAL02 to shorten the need for costly critical care management, overall hospital stays, improve patient outcomes and provide physicians with a powerful tool to manage SCABP complications and control infections; the Company's ability to develop innovative medicines that result in meaningful improvements in patients' lives; statements regarding potential regulatory exclusivity, CAL02's potential eligibility for fast track and breakthrough therapy designations, potential for a CAL02 new drug application for the treatment of SCABP to qualify for priority review and potential strengthening of the patent portfolio for this asset; and the potential of the Company's pipeline and product candidates to address underserved therapeutic areas

across multiple disease states. 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, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 2022, 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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

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[1] Blasi, F., Mantero, M., Santus, P., & Tarsia, P. (2012). Understanding the burden of pneumococcal disease in adults. *Clinical Microbiology and Infection*, *18*, 7-14.

[2] Jain, S., Self, W. H., Wunderink, R. G., Fakhran, S., Balk, R., Bramley, A. M., ... & Finelli, L. (2015). Community-acquired pneumonia requiring hospitalization among US adults. *New England Journal of Medicine*, *373*(5), 415-427.