Eagle Pharmaceuticals Announces FDA Acceptance of Investigational New Drug Application for CAL02, a Novel First-in-Class Broad-Spectrum Anti-Virulence Agent for the Adjunct Treatment of Severe Community-Acquired Bacterial Pneumonia

November 14, 2022

-- Expect to begin a Phase 2 study in approximately 276 patients with severe community-acquired pneumonia at approximately 120 sites worldwide --

-- Patient enrollment expected to commence as early as the beginning of 2023 --

-- CAL02 is being developed as an adjunct to the clinically indicated antibiotic treatment --

WOODCLIFF LAKE, N.J., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") announced today that the U.S. Food and Drug Administration ("FDA") has accepted its investigational new drug ("IND") application for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the adjunct treatment of severe community-acquired bacterial pneumonia ("SCABP").

The Phase 2 study is expected to begin enrollment of approximately 276 patients with severe community-acquired pneumonia at approximately 120 sites worldwide as early as the beginning of 2023.

"We are pleased that the CAL02 IND has been accepted by FDA and look forward to commencement of the Phase 2 study anticipated early in 2023. We already have identified a pool of eligible sites across 22 countries, which we believe could yield approximately 120 sites worldwide," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "This is an exciting program, and we believe that CAL02 has the potential to improve the treatment regimen for patients with severe community-acquired pneumonia, as well as to shorten the duration of illness and improve patient outcomes," concluded Tarriff.

CAL02 is potentially eligible 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.

Investor Day Registration Information

Eagle will host an Investor Day on Tuesday, December 6, 2022, at the Lotte New York Palace Hotel, at 8:00am ET.

The program will provide an opportunity for an in-depth look at the Company's hospital-based products and product candidates, including CAL02, BARHEMSYS® and BYFAVO®, landiolol, and Enalare's ENA-001. Featured speakers include Scott Tarriff, President and Chief Executive Officer, senior members of Eagle's clinical and commercial teams, and noteworthy Key Opinion Leaders, who will discuss the scientific rationale and potential unmet medical needs for each pipeline asset and commercial product.

Advance registration is required for this event. Institutional investors and analysts are kindly requested to RSVP through this link to attend.

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, statements regarding the Company's expectations for the design and timing of the planned Phase 2 study, including with respect to enrollment and site selection and the timing thereof; statements regarding the potential of CAL02 to be a medical breakthrough and offer unique therapeutic benefits to seriously ill patients, potentially improving the treatment regimen for patients with severe community-acquired pneumonia, shortening the duration of illness and improving patient outcomes; statements regarding potential regulatory exclusivity, CAL02's potential eligibility for fast track and breakthrough therapy designations and the potential for a CAL02 new drug application for the treatment of SCABP to qualify for priority review; statements regarding the Company's expectation to strengthen the patent portfolio for CAL02; 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 Reports on Form 10-Q for the quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, filed with the SEC on May 9, 2022, August 9, 2022, and November 9, 2022, respectively, 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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