Eagle Pharmaceuticals to Present CAL02 Trial in Progress at the 2023 ASM/ESCMID Joint Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance

September 11, 2023

-- CAL02 is a unique therapeutic agent that is designed to work differently from antibiotics, aiming to disarm an infectious pathogen's virulence factors to reduce damage and mitigate disease --

-- The first-in-human study showed positive safety and efficacy when added to standard of care in patients with severe community-acquired bacterial pneumonia --

Valentin Curt, MD

Senior Vice President, Clinical Drug Development and Interim Chief Medical Officer at Eagle Pharmaceuticals

WOODCLIFF LAKE, N.J., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that its abstract describing the global in-progress Phase 2 study of CAL02, a first-in-class, broad-spectrum, anti-virulence agent under development as an adjunct to antibiotic therapy for the treatment of severe community-acquired bacterial pneumonia ("SCABP"), has been selected for a poster presentation at the conference co-sponsored by the American Society for Microbiology ("ASM") and the European Society for Clinical Microbiology and Infectious Diseases ("ESCMID"). This prestigious, multidisciplinary meeting is focused on the challenges, opportunities, and current requirements for antimicrobial drug development to address antimicrobial resistance. The conference is scheduled to take place September 19-22, 2023, in Boston, Massachusetts.

"We are pleased to have the opportunity to present additional details of the CAL02 study in progress to our esteemed colleagues," stated Valentin Curt, MD, Senior Vice President, Clinical Drug Development and Interim Chief Medical Officer at Eagle Pharmaceuticals. "Inclusion at this scientific

congress supports the significance of the potential clinical value of CAL02 to address a large, unmet medical need. Antimicrobial resistance is one of the world's most urgent public health challenges, and SCABP is a prevalent infectious disease associated with high morbidity and mortality, despite the availability of vaccines, effective antibiotic regimens, and state-of-the-art critical care therapy. CAL02 has the potential to mitigate organ damage, pro-inflammatory responses, and to facilitate killing the underlying pathogen, without contributing to antibiotic resistance We look forward to sharing details of the study, its progress, as well as of CAL02's potential to redefine the treatment of SCABP without contributing to antibiotic resistance," concluded Curt.

Details of the poster presentation are as follows:

Abstract

Title: A Randomized, Double-Blind, Placebo Controlled Multicenter Study to Evaluate the Efficacy and Safety of CAL02 Administered Intravenously in Addition to Standard of Care (SOC) in Subjects with Severe Community-Acquired Bacterial Pneumonia (SCABP)

Date: **September 20, 2023**
Time: **3:35pm ET**
Location: Poster Presentations Session I

In June 2023, the U.S. Food and Drug Administration ("FDA") granted Qualified Infectious Disease Product ("QIDP") Designation and Fast Track Designation for CAL02, entitling Eagle to an additional five years of marketing exclusivity upon approval. Eagle believes that CAL02 could also be eligible for breakthrough therapy and new chemical entity ("NCE") designations, which would result in five years of marketing exclusivity upon approval or three years without NCE designation, resulting in a total potential of eight or ten years of exclusivity.

In July 2023, the first patients were randomized in a multi-center adaptive, randomized, double-blind, placebo-controlled Phase 2 study designed to assess the efficacy and safety of CAL02 administered intravenously in addition to standard of care in patients with SCABP. The study plans to enroll approximately 276 patients with SCABP worldwide. Additional details are available on ClinicalTrials.gov (Identifier: NCT05776004). Depending upon recruitment rates, Eagle anticipates having its 50% interim report around the first half of 2024.

Eagle is also further developing the patent estate to protect the intellectual property resulting from the development of CAL02. CAL02 is currently protected by issued U.S. Patent No.10,744,089, which extends until September 2035, and may be eligible for Patent Term Extension for up to five years until 2040.

About CAL02
CAL02 is an investigational, innovative, first-in-class anti-infective agent that acts as a competitive decoy, or lure, for bacterial virulence factors, which contribute to infection-related complications, sepsis, septic shock, and death. CAL02 consists of proprietary liposomes engineered to capture the virulence factors produced by a broad range of Gram-positive and Gram-negative bacteria causing severe infectious diseases, including severe pneumonia. CAL02 is poised to play a key role in the fight against anti-microbial resistance. Its action is complementary to that of antibiotics, and it does not appear to exert any selective pressure, which can contribute to antibiotic resistance. Because of these characteristics, CAL02 could be administered empirically in combination with standard of care as soon as patients show signs of severe pneumonia. Clinical results to date underscore the potential of CAL02 to transform the standard of care and to dramatically reduce the time and the cost of care for millions of critically ill SCABP patients. Eagle has a worldwide exclusive license on CAL02 acquired from Combioxin SA.

About Virulence Factors
Virulence is a bacteria's ability to infect a host and produce disease. Virulence factors are produced by a variety of pathogens and assist in potentiating infection, evading and suppressing the immune system, and damaging host cells, including immune cells, and organs. Blocking the activities of virulence factors is a new approach that has emerged over the last decade. Anti-virulence drugs, a new class of drugs, target virulence factors of pathogens, effectively disarming infectious pathogens.

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," "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 with respect to: the Company's ability to develop innovative medicines that address unmet medical needs; 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 or meaningful 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 post- COVID-19 environment and geopolitical factors such as the conflict in Ukraine; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates and successful compliance with FDA, 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 product candidates; the success of the Company's relationships with its partners; 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; competition from other pharmaceutical and biotechnology companies and the potential for 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; 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, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, the Company's Quarterly Report on Form 10-Q 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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A photo accompanying this announcement is available at:
https://www.globenewswire.com/NewsRoom/AttachmentNg/30193350-3287-4ef3-bc42-cdd688fef55c