Eagle Pharmaceuticals Announces a Trial in Progress Presentation of Phase 2/3 Study of Intravenous Amisulpride as Prevention of Postoperative Nausea and Vomiting in Pediatric Patients at the Upcoming Society for Ambulatory Anesthesia (SAMBA) 2024 Annual Meeting

April 30, 2024

Preliminary results from the Company's ongoing Phase 2/3 study expected in the first half of 2025

WOODCLIFF LAKE, N.J., April 30, 2024 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it will deliver a Trial in Progress presentation discussing the ongoing Phase 2/3 study of intravenous amisulpride as a prevention of postoperative nausea and vomiting (PONV) in pediatric patients from birth (full-term) until 17 years of age at the upcoming Society for Ambulatory Anesthesia (SAMBA) 2024 Annual Meeting, which is being held May 2-4, 2024, in Savannah, Georgia.

"Evaluating nausea in children remains a challenging and complex process," stated Mike Greenberg, MD, Vice President of Medical Affairs at Eagle Pharmaceuticals. "We are therefore pleased to have this opportunity to share the details of our ongoing Phase 2/3 study evaluating amisulpride to prevent postoperative nausea and vomiting in pediatric patients at this year's SAMBA 2024 Annual Meeting. Through this study, we hope to demonstrate the potential benefit of amisulpride therapy in this pediatric patient population, and we look forward to presenting preliminary results from this study in the second half of 2025."

Details of the presentations are as follows:

Abstract Title:	**Randomized, Double-Blind, Parallel-Group Active-Controlled Phase 2/3 Study of Intravenous Amisulpride as Prevention of Postoperative Nausea and Vomiting in Pediatric Patients: Trial in Progress**
Date:	**Thursday, May 2, 2024**
Times:	**5:10-6:10pm**
Presenter:	**Dr. Lynn Bichajian**

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," "intend," "remain," "potential," "prepare," "expect," "believe," "plan," "seek," "continue," "estimate," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, the potential benefits and usefulness of amisulpride/Barhemsys, including its potential to prevent postoperative nausea and vomiting in pediatric patients; expectations with respect to clinical trials including timing and results thereof; and the potential of 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: trial results may not be indicative of future trial results or commercial results; the completion of the review and preparation of the Company's financial statements and internal control over financial reporting and disclosure controls and procedures and the timing thereof; the discovery of additional information; further delays in the Company's financial reporting, including as a result of unanticipated factors; the Company's ability to comply with its obligations under its credit agreement; the possibility that the Company will be unable to regain compliance with, or thereafter continue to comply with, the Nasdaq Listing Rules, or experience violations of additional Nasdaq Listing Rules; the possibility that the Nasdaq may delist the Company's securities; the Company's ability to remediate material weaknesses in its internal control over financial reporting; the Company's ability to recruit and hire a new Chief Executive Officer and new Chief Financial Officer; the ability of the Company to realize the anticipated benefits of its plan designed to improve operational efficiencies and realign its sales and marketing expenditures and the potential impacts thereof; the impacts of the post- COVID-19 environment and geopolitical factors such as the conflicts between Russia and Ukraine and Gaza and Israel; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates and successful compliance with Federal Drug Administration, 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 products; the success of the Company's relationships with its partners; the outcome of litigation; 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 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; risks inherent in estimates or judgments relating to the Company's critical accounting policies, or any of the Company's estimates or projections, which may prove to be inaccurate; 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 estimates, 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 SEC on March 23, 2023, the Company's Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, and 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.

Indication and Important Safety Information for Barhemsys® (amisulpride) Injection[4]

Indication
Barhemsys is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated in adults for prevention of PONV either alone or in combination with an antiemetic of a different class and treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

Important Safety Information

Contraindication
Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation
Barhemsys causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid Barhemsys in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions
The most common adverse reaction, reported in ≥ 2% are:

- Prevention of PONV: increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension.
- Treatment of PONV: infusion site pain.

To report SUSPECTED ADVERSE REACTIONS, contact Acacia Pharma at 1-877-357-9237 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Use in Specific Populations

Pregnancy
Available data with amisulpride use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation
Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

Barhemsys may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after Barhemsys treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of Barhemsys.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Drug Interactions

- Barhemsys causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of Barhemsys in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and Barhemsys. Avoid using levodopa with Barhemsys.

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

Timothy McCarthy
LifeSci Advisors, LLC
T: 917-670-9282
E: tim@lifesciadvisors.com

Public Relations for Eagle Pharmaceuticals, Inc.:
Faith Pomeroy-Ward
T: 817-807-8044
E: faith@eagleus.com