Eagle Pharmaceuticals and Enalare Therapeutics Announce Additional Award Worth Up to $50 Million from BARDA to Advance an Intramuscular ("IM") Formulation of ENA-001

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-- ENA-001, a new chemical entity with a unique mechanism of action, is being developed as an agnostic respiratory stimulant for use in multiple patient populations experiencing acute respiratory depression --

-- Development is under way of intramuscular formulation for treatment of community drug overdose and as a medical countermeasure for mass casualty events --

-- Expanded funding supports development of an IM formulation of ENA-001 from pre-clinical toxicology through filing for FDA approval for use in the United States --

WOODCLIFF LAKE, N.J. and PRINCETON, N.J., Sept. 27, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") and Enalare Therapeutics Inc. ("Enalare") today announced that Enalare has secured a contract for up to $50.3 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services (contract number 75A50122C00072). In partnership with BARDA, ENA-001 is being developed in an intramuscular ("IM") formulation for potential use in patients experiencing community drug overdose and as a potential medical countermeasure for mass casualty events.

The contract is awarded in stages based on the achievement of established milestones and deliverables and provides funding for Enalare to perform pre-clinical toxicology studies, human clinical studies, drug and device manufacturing, and submission of the regulatory file to the U.S. Food and Drug Administration ("FDA") for a formulation of ENA-001 suitable for community use. The first phase of the contract, which provides approximately $6.0 million to complete activities through the initial Phase 1 study, coincides with grant support from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health.

"Respiratory depression can be life threatening. This award provides critical non-dilutive funding to Enalare to accelerate the development of an IM formulation for ENA-001, which could potentially enable more rapid deployment in emergency situations. The pre-clinical work is going very well, and the BARDA contract provides support along the development and regulatory pathway toward FDA approval of ENA-001 for use in the United States. We believe this is a promising opportunity to address a serious, unmet issue in our society, and adds further to our enthusiasm for our agreement with Enalare," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We are pleased to expand our partnership with BARDA on the development of ENA-001 – a novel compound with a unique mechanism of action as an agnostic respiratory stimulant," said Herm Cukier, President and CEO of Enalare Therapeutics. "ENA-001's rapid and proven ventilatory stimulation, irrespective of the cause of the respiratory depression, is critical for effective post-exposure therapy given the urgency for treatment and the unknowns associated with many chemical threats. Drug overdoses continue to ravage our communities, and with this new contract, we can accelerate our efforts to achieve our mutual goal of developing an innovative and rapid treatment for respiratory depression in a variety of settings," concluded Cukier.

The new award builds on an existing partnership between Enalare and the BARDA DRIVe ReDIRECT (Repurposing Drugs in Response to Chemical Threats) program. During that project, Enalare performed work to develop a formulation of ENA-001 that is suitable for intramuscular administration, which is much preferred for emergency use in the community.

The funding is provided via Biomedical Advanced Research and Development Authority to support the advanced research and development of medical countermeasures (MCM) for chemical, biological, radiological and nuclear (CBRN) agents, pandemic influenza, and emerging infectious diseases that threaten the U.S. civilian population.

In August 2022, Eagle made an equity investment of $12.5 million in Enalare, with a commitment to invest another $12.5 million six months later and two potential follow-on equity investments of $15 million each contingent upon (i) the commencement of the ENA-001 Phase 2 clinical trial, and (ii) the ENA-001 Phase 2 clinical trial reaching 50% enrollment. Eagle also has the option to acquire the remaining Enalare shares for an aggregate purchase price ranging from $100-$175 million plus royalty rights ranging from 9%-12% on all future global net sales of any Enalare product, paid to the ex-Eagle holders of Enalare shares at the time of acquisition.

The development of ENA-001 is also supported by the National Institute on Drug Abuse ("NIDA") of the National Institutes of Health ("NIH") under award number R44DA057133. The content of this document is the responsibility of its authors and does not necessarily represent the official views of the National Institutes of Health.

About ENA-001

Enalare's lead compound, ENA-001, is a one-of-a-kind new chemical entity (NCE) designed as an agnostic respiratory stimulant. The compound has a novel mechanism of action that affects ventilation via the peripheral chemoreceptor pathways in the carotid body. It utilizes the body's own ventilation control system to beneficially influence breathing and has been shown to be effective and well tolerated in five human studies to date. With its novel mechanism of action and based on findings to date, it could potentially improve the lives of those impacted by several life-threatening conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. ENA-001 is an investigational compound and is not approved for use by the FDA.

About Enalare Therapeutics Inc.

Enalare Therapeutics Inc. is a clinical-stage biopharmaceutical company dedicated to developing novel therapies for patients suffering from

life-threatening acute respiratory and critical care conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. Enalare maintains global rights to its novel compounds and intends to start additional clinical trials with ENA-001 for several indications in the near term.

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 with respect to the development of, potential benefits of and potential FDA submission for ENA-001, including a potential IM formulation that could potentially enable more rapid deployment in emergency situations and the potential to develop an innovative and rapid treatment for respiratory depression in a variety of settings; expectations with respect to the BARDA award providing funding to Enalare to accelerate the development of ENA-001, including the potential receipt of contingent funding from BARDA by Enalare; the achievement of milestones and deliverables; the potential further investment by Eagle in Enalare; and Eagle's development programs, products and pipeline. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's or Enalare'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 or Enalare'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; the ability of Enalare to achieve milestones and deliverables under the BARDA agreement and otherwise accelerate and achieve successful results in the development of ENA-001; 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, which the Company expects to file with the SEC on August 9, 2022. 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