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Evoke Successfully Completes Phase 3 Clinical Trial Enrollment of EVK-001 in Women with Symptoms Associated with Diabetic Gastroparesis

SOLANA BEACH, Calif., April 25, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), today announced that it has successfully completed patient enrollment in its pivotal Phase 3 clinical trial of EVK-001, its patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

The four-week, U.S. multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial is evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in approximately 200 adult female subjects with diabetic gastroparesis. The primary endpoint is the change from baseline in symptom score at week 4 utilizing a proprietary Patient Report Outcome (PRO) instrument.

"Completing enrollment of our Phase 3 clinical trial of EVK-001 is a monumental step for Evoke, and based on discussions with the FDA, this pivotal trial is the final study necessary to submit a New Drug Application (NDA)," said Dave Gonyer, R.Ph., President and CEO. "We remain confident in the success of our Phase 3 trial based on the positive results from our large Phase 2b study which demonstrated safety and statistically significant symptom improvement in women, who make up 80% of all patients with gastroparesis."

Mr. Gonyer continued, "While completing enrollment in the Phase 3 clinical trial, we have been preparing to submit an NDA as soon as possible, should the results of the study be positive. Importantly, we completed a Thorough ECG (TQT) study, which demonstrated that therapeutic and supratherapeutic doses of EVK-001 did not adversely affect the QT interval in healthy subjects, and we have produced EVK-001 at commercial scale in accordance with the FDA standards for chemistry, manufacturing and controls. These data will be submitted as part of our NDA package. This is a very exciting time for Evoke as our strategic planning and progress to-date have placed us in an optimal position to quickly move toward potential commercialization."

About Evoke Pharma, Inc.
Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The Company is developing EVK-001, a metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal administration. Visit www.EvokePharma.com for more information.

Safe Harbor Statement

Evoke cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "or expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding: the timing of data from the Phase 3 clinical trial of EVK-001 and the potential to replicate the results observed in the prior Phase 2b study; the sufficiency of such data and the other activities completed to data providing a basis for the submission of an NDA for EVK-001 to the FDA and the timing thereof; and the potential commercialization of EVK-001. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risk and uncertainties inherent in Evoke's business, including, without limitation: the inherent risks of clinical development of EVK-001 and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be

predictive of the safety and efficacy results in the Phase 3 clinical trial; Evoke will require substantial additional funding to potentially commercialize EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; and other risks detailed in Evoke's prior press releases and in the periodic reports it files with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Evoke undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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