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Evoke Announces Timing of Phase 3 Results from its Recently Fully Enrolled Pivotal Clinical Trial of EVK-001

SOLANA BEACH, Calif., May 03, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK) today announced that it expects to provide top line data results from its pivotal Phase 3 clinical trial of EVK-001 in women with symptoms associated with diabetic gastroparesis early in the third quarter of 2016. The study was designed to enroll approximately 200 subjects and the Company has confirmed that 205 subjects have now been randomized in the trial. EVK-001 is the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

Dave Gonyer, R.Ph., President and CEO stated, "Having completed enrollment in our pivotal Phase 3 trial of EVK-001, we expect to provide top line results early in the third quarter. We are excited to have completed enrollment in this important study and look forward to presenting our data in the near term. As we have previously stated, Evoke has assembled a team and begun preparation for a New Drug Application (NDA) and this is the last key component necessary. We believe there is a substantial need for an improved drug treatment option for patients with gastroparesis, which provides Evoke and EVK-001 with a promising opportunity to enter a large market in which our drug can have a significant impact."

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

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; 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; the potential commercialization of EVK-001; and the market size for EVK-001 and its impact on such market. 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, and Evoke cannot be certain that it will be able to obtain regulatory approval for 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; Evoke may not be able to successfully commercialize EVK-001, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; 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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