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

205 subjects complete the study

SOLANA BEACH, Calif., June 01, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), today announced that the last subject completed treatment in its pivotal Phase 3 study for EVK-001, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. The primary endpoint in the four-week, U.S. multicenter, randomized, double-blind, placebo-controlled clinical trial is the change in gastroparesis symptoms at week 4 utilizing a proprietary Patient Report Outcome (PRO) symptom assessment instrument. The Company expects to report top-line Phase 3 study results early in the third quarter of 2016.

"This is an exciting time for Evoke now that the last subject has completed their final treatment in our pivotal Phase 3 trial of EVK-001," said Dave Gonyer, R.Ph., President and CEO. "This is an important study, not only for the Company, but also potentially for the gastroparesis community as a whole. In addition to offering a new treatment option for a disease with a significant unmet need, the results could help influence how gastroparesis treatments should be evaluated in future trials as well."

Mr. Gonyer continued, "Since there are no further patient visits, our clinical team can now focus on reviewing blinded data to confirm outstanding questions have been addressed prior to database lock. After this work is complete, we expect to be able to report the topline data to the public. Given the progress we have made to date, we believe we will be ready to move forward with our New Drug Application (NDA) in the near term, should we receive positive data from this trial."

About the Phase 3 Clinical Trial (METO-IN-003)
The METO-IN-003 study is a randomized, double-blind, two-arm, placebo-controlled, Phase 3 clinical trial of nasal metoclopramide (EVK-001) in female patients with diabetic gastroparesis. The primary objective of the study is to demonstrate that EVK-001 reduces symptoms associated with diabetic gastroparesis in female subjects over a 28 day period, as determined by a patient reported outcome measurement system. A total of 205 patients, ages 18 to 75, were enrolled in METO-IN-003. Secondary efficacy endpoints include symptom improvement in individual symptoms associated with diabetic gastroparesis.

About Gastroparesis
Gastroparesis is a disease defined by an inability or delay of normal stomach peristalsis and emptying. It is believed to be caused by insult or injury to the vagus nerve. This is frequently due to long-standing, poorly controlled diabetes, infectious disease and other causes. Currently, there are 2 to 3 million patients being treated for the disease in the U.S. with another 10+ million that suffer without treatment. There is only one U.S. Food and Drug Administration (FDA) approved drug used to treat this large and growing market, metoclopramide. Unfortunately, the only currently available method of taking this medication outside of the hospital is with an oral tablet. This delivery is suboptimal due to the delayed gastric emptying that defines the disease, making absorption of any oral medication unpredictable for patients that suffer from gastroparesis. Evoke is developing the EVK-001 nasal delivery formulation of metoclopramide to bypass the issues of gastric delay and provide predictable treatment for persons suffering from this disorder.

About Evoke Pharma, Inc.
Evoke is a specialty pharmaceutical company based in San Diego, focused primarily on the development of drugs to treat gastrointestinal disorders and diseases. 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; and 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. 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 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 completed a Phase 3 clinical trial and continues enrollment in a 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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