December 2, 2014

Evoke Pharma's EVK-001 Showed No QT Prolongation in Thorough ECG (TQT) Study

SOLANA BEACH, Calif., Dec. 2, 2014 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced results from an electrocardiogram (ECG) study that assessed the potential of metoclopramide nasal spray (EVK-001) to increase the cardiac QT and corrected QT (QTc) interval across a range of plasma concentrations. The study was conducted to satisfy a safety requirement by the U.S. Food and Drug Administration (FDA) in support of the submission of a New Drug Application (NDA) for EVK-001, an investigational medication for relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. The study met the pre-specified primary endpoint, demonstrating that EVK-001, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects.

The QT interval represents the amount of time the heart's electrical system takes to repolarize, or recharge, after each beat. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. A TQT study is a specialized clinical trial designed to assess whether an investigational medication has the potential to prolong the QT interval.

This randomized, double-blind, double-dummy, four-way crossover TQT study, designed in accordance with the FDA's published guidance on clinical evaluation of QT/QTc interval, compared the effects of EVK-001 on the QT/QTc interval when administered at therapeutic and supratherapeutic doses in 48 healthy female and male volunteers. Moxifloxacin, an antibiotic known to prolong the QT/QTc interval, was used as the positive control.

"We are very pleased with the findings from this study. It represents another important milestone for the Company as we have now successfully completed one of two studies required for submission of our NDA," said Dave Gonyer, President and CEO of Evoke. Mr. Gonyer added, "We continue to be dedicated to the successful development of our lead product candidate EVK-001 for the relief of symptoms associated with diabetic gastroparesis via a novel intranasal drug delivery system. With these results showing the drug has no clinically significant impact on cardiac conduction, we are solely focused on completing enrollment of our Phase 3 clinical trial for EVK-001 and look forward to announcing results from that trial in the coming year."

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 intranasal administration.

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," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative 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 results from the Phase 3 clinical trial 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, including potential delays in enrollment and completion of clinical trials and studies, including the Phase 3 clinical trial; Evoke will require substantial additional funding, including potentially to complete the Phase 3 clinical trial of EVK-001 as well as finance additional development requirements, and may be unable to raise capital when needed; 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 or any other future trial; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; 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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Source: Evoke Pharma