

February 17, 2016

Evoke Pharma to Present Results From Successful Thorough ECG (TQT) Study of EVK-001 at Digestive Disease Week 2016

Clinical Data Support Cardiac Safety of EVK-001

SOLANA BEACH, Calif., Feb. 17, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that data from the Company's successful thorough electrocardiogram (ECG) study of EVK-001, its metoclopramide nasal spray product candidate, were accepted for presentation at Digestive Disease Week 2016. As previously announced, this thorough ECG study demonstrated that EVK-001 did not prolong the cardiac QT and corrected QT (QTc) intervals in healthy subjects across a range of plasma concentrations.

Evoke designed the study in accordance with published FDA and ICH guidance on the clinical evaluation of QT/QTc interval prolongation and the proarrhythmic potential of non-cardiac drugs. The QT interval represents the amount of time the heart's electrical system takes to repolarize, or recharge, after each beat, and prolongation of the interval may increase the risk for cardiac arrhythmias.

Marilyn R. Carlson, DMD, MD, Chief Medical Officer, stated, "We are very pleased with how our product performed in this thorough QT/QTc study and we are excited to have the results accepted for presentation at the upcoming Digestive Disease Week meeting in San Diego. These cardiac safety data provide clinically meaningful information for physicians treating diabetic patients with multiple medical problems, in addition to gastroparesis. We believe that the acceptance of these data for presentation to this important body of GI scientists and clinicians is a reflection of the importance of the cardiac safety profile of new drug formulations."

The randomized, double-blind, double-dummy, four-way crossover study investigated the effects of therapeutic and supratherapeutic doses of EVK-001 on the QT/QTc interval in 48 healthy female and male volunteers. Moxifloxacin, an antibiotic known to prolong the QT/QTc interval, was included as the positive control.

The thorough QT/QTc study was conducted for inclusion in the New Drug Application (NDA) for EVK-001 to fulfill an end of phase 2 meeting request from the FDA. As stated in the FDA's guidance, "adequate premarketing investigation of the safety of a new pharmaceutical agent should include rigorous characterization of its effects on the QT/QTc interval."

The Company is also currently conducting a phase 3 clinical trial of EVK-001 for treatment of symptoms associated with diabetic gastroparesis in women. This trial is expected to fully enroll in the first half of 2016 and allow Evoke to move forward with the NDA submission.

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. Visit <u>www.EvokePharma.com</u> 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 forwardlooking 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 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 enrollment completion of Evoke's ongoing Phase 3 clinical trial of EVK-001 and the submission of an NDA to the FDA. 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 delays in enrollment 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 complete the Phase 3 clinical trial and 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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