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Evoke Pharma Announces the Completion of Enrollment in Its Thorough ECG Study for EVK-001

SOLANA BEACH, Calif., Sept. 9, 2014 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has completed enrollment in its thorough ECG (QT) study of EVK-001, the Company's lead product candidate. EVK-001 is currently in a Phase 3 clinical trial for the relief of symptoms associated with acute and recurrent gastroparesis in women with diabetes mellitus.

The study is fully enrolled with 48 patients, ahead of the Company's original projected timeframe. "Consistent with our continued commitment to the efficient clinical development of EVK-001, we initiated and completed enrollment of this study ahead of schedule," stated Dave Gonyer, President and CEO of Evoke. Mr. Gonyer continued, "Given the full enrollment status, we now expect to provide top-line data from the study later this year rather than in 2015."

The double-blind, double-dummy, four-way crossover ECG (electrocardiogram) study in healthy volunteers is designed to evaluate the effect of EVK-001 on cardiac ventricular repolarization, specifically the QT-interval. Prior to the study initiation, the study protocol was submitted to the U.S. Food and Drug Administration (FDA) for their review. The study is being conducted to meet one of the two remaining trials requested by the FDA as requirements for submission of a New Drug Application for EVK-001.

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 top-line data from the thorough ECG study. 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 thorough ECG study; the risk that the results of the thorough ECG study may not replicate the cardiovascular safety profile observed in patients administered with metoclopramide to date; 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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