August 12, 2014

Evoke Pharma Announces Initiation of a Thorough ECG (QT) Study for EVK-001

SOLANA BEACH, Calif., Aug. 12, 2014 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the initiation of its thorough ECG (QT) study of the Company's lead product candidate, EVK-001, which 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 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. Designed in accordance with U.S. Food and Drug Administration (FDA) E14 Guidance, the study protocol has been reviewed by the FDA and is being conducted in order to meet the FDA's requirements for submission of a New Drug Application (NDA) for EVK-001.

Marilyn R. Carlson, DMD, MD, RAC, Chief Medical Officer of Evoke, commented, "We are pleased to have initiated the thorough ECG study of EVK-001, our intranasal delivery formulation of metoclopramide for the treatment of women with diabetic gastroparesis. This brings us another step closer to fulfilling the requirements for the EVK-001 NDA."

Dr. Carslon continued, "Since the oral formulation of metoclopramide was first approved in 1980, millions of doses have been administered to patients of all ages for a range of indications with no signs that there are cardiovascular safety issues associated with the drug. With the thorough ECG (QT) study now underway, we expect to be able to provide top-line data in early 2015."

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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Source: Evoke Pharma