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Evoke Pharma Initiates Phase 3 Clinical Trial of EVK-001 for Treatment of Gastroparesis

First Patient Enrolled in Study of Novel Intranasal Formulation and Delivery of Metoclopramide

SOLANA BEACH, Calif., April 22, 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 Phase 3 clinical trial investigating the use of EVK-001, a novel metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

"We are very pleased to have our Phase 3 clinical trial for EVK-001 underway with the enrollment of our first patient into the study," said David Gonyer, R.Ph., President and Chief Executive Officer of Evoke Pharma. "Our goal is to address an important unmet need in treating gastroparesis: a therapy that can improve the GI symptoms, including nausea and vomiting, that are characteristic of this disorder. Building on our successful Phase 2 placebo-controlled study, this Phase 3 study is designed to confirm the results that showed EVK-001 is an effective and well-tolerated drug candidate for women with diabetic gastroparesis."

"Gastroparesis in patients with diabetes can be very difficult to treat. There are limited FDA-approved options and the absorption of oral medications can be unpredictable," said lead investigator Dr. Henry P. Parkman, Director of the GI Motility Laboratory at the Temple University School of Medicine. "EVK-001 has shown promising safety and efficacy results in previous diabetic gastroparesis studies and may provide a valuable treatment alternative for this patient population. Unlike oral medications, intranasal delivery bypasses the GI tract and directly enters the bloodstream, allowing predictable absorption regardless of the gastric emptying delays and symptom flares associated with the disease."

Gastroparesis is a disorder in which the stomach is delayed in emptying its contents to the small intestine (in the absence of an obstruction). Characteristic symptoms are nausea, vomiting, abdominal pain, early satiety and bloating. Gastroparesis interferes with absorption of food and medications in the GI tract due to unpredictable gastric emptying and vomiting. Symptom flares vary in severity and diminish quality of life, negatively impact blood glucose control, and may lead to complications requiring hospitalization. The potential gastroparesis patient pool in the United States is approximately 12 to 16 million adults, with women making up over 80% of the affected population.

The Phase 3 clinical trial is a four-week, multicenter, placebo-controlled, double-blind, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis and is expected to enroll 200 patients at sites across the United States. The trial is expected to be completed in 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 diabetic 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 ability of EVK-001 to address an important, unmet medical need; the enrollment and completion of the Phase 3 clinical trial; and the market opportunity for 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 or the presentation 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, including the Phase 3 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; the ability of Evoke to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its product candidate and the ability to operate its business without infringing the intellectual property rights of others; competition from other pharmaceutical or biotechnology companies; 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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