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Evoke Pharma Announces Publication of Clinical Data Demonstrating EVK-001 Significantly Improves Symptoms in Women With Diabetic Gastroparesis

Second Phase 2 Trial Demonstrates Effectiveness of Intranasal Metoclopramide Spray

SOLANA BEACH, Calif., June 24, 2015 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that previously disclosed results from its Phase 2b clinical trial evaluating EVK-001, its patented intranasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women, have been published in the July issue of [Clinical Gastroenterology and Hepatology](#), a leading peer-reviewed journal published by the American Gastroenterological Association (AGA).

Henry P. Parkman, M.D., Director of the GI Motility Laboratory at the Temple University School of Medicine, commented, "These Phase 2 data demonstrate EVK-001's potential as an effective treatment that is well-tolerated by women suffering from diabetic gastroparesis. Approximately 80% of all diagnosed diabetic gastroparesis patients are women. This is not surprising given that women have shown to have slower gastric emptying when compared to men, a difference in genders that has been well established in the medical community.

"Overall, data from controlled clinical trials continue to show that Evoke's novel intranasal spray is an optimal route of administration for these patients who have few treatment options. Unlike oral formulations that can have erratic absorption from the GI tract, EVK-001's absorption is not impaired by delayed gastric emptying and symptoms, such as vomiting. This is especially important during gastroparesis symptom flares."

The US multicenter, double-blind, randomized Phase 2b study enrolled and dosed 285 patients (71% female) with type 1 or type 2 diabetes and a previous diagnosis of gastroparesis. The pre-specified efficacy endpoints evaluated the response to treatment in male subjects and female subjects separately. In female subjects, gastroparesis symptom scores showed a statistically and clinically significant improvement when given EVK-001 compared with placebo. In male subjects, EVK-001 was not shown to improve symptom scores when compared to placebo. There were no drug-related serious adverse effects reported during the study and the most common adverse events were altered taste, headache, and fatigue.

Marilyn Carlson, D.M.D., M.D., RAC, Evoke's Chief Medical Officer, said, "Collectively, our two Phase 2 diabetic gastroparesis studies confirm the effectiveness, absorption, and tolerability of Evoke's patented formulation of metoclopramide when delivered as a nasal spray. Importantly, results from our Phase 2b study further establish that EVK-001 provides clinically meaningful benefits for female patients, rather than male, and that patient gender is predictive of EVK-001's benefits. These data subsequently served as the basis for our agreement with the FDA to focus our currently ongoing Phase 3 trial on women with symptomatic diabetic gastroparesis."

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 www.EvokePharma.com 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 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 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, the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis and Evoke's completed and ongoing trials and studies serving as a basis for submission of an NDA and the sufficiency of Evoke's resources to fund operations through 2015. 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: 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; the inherent risks of clinical development of EVK-001, including continued delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke may spend its available cash faster than it anticipates; 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; 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.

CONTACT: Investor / Media Contact:

The Ruth Group

David Burke / Kirsten Thomas

Tel: 646-536-7009 / 7014

dburke@theruthgroup.com / kthomas@theruthgroup.com

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