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Evoke Pharma Presents Gimoti Efficacy and Safety Data from Phase 3 Trial as Late Breaker at Digestive Disease Week 2017

Data Demonstrate Gimoti Significantly Improves Symptoms in Women with Moderate to Severe Diabetic Gastroparesis

SOLANA BEACH, Calif., May 10, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that data from its Phase 3 trial of Gimoti™, its patented nasal delivery of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women, were presented at the Digestive Disease Week® (DDW) 2017 Meeting held in Chicago, Illinois.

The poster presentation entitled *"Symptom Severity Influences Drug Efficacy in Women with Diabetic Gastroparesis: Results of a Phase 3 Study with Metoclopramide Nasal Spray"* illustrated that patients with moderate to severe symptoms at study entry, which included 105 of the 205 patients (51%) enrolled in the study, responded clinically and statistically significantly better to Gimoti than placebo at multiple time points in the Intent-to-Treat (ITT) and Per Protocol populations. Focusing on the benefits in patients with moderate to severe symptoms is consistent with the U.S. Food and Drug Administration (FDA) guidance on the clinical evaluation of drugs for the treatment of gastroparesis issued in July 2015 (Gastroparesis: Clinical Evaluation of Drugs for Treatment, Draft Guidance).

In the Phase 3 trial, Gimoti was particularly effective in reducing nausea and upper abdominal pain, the most common and debilitating symptoms in patients with moderate to severe symptoms. This was similar to the benefits experienced by female patients in the Company's Phase 2b trial. Safety data from the Phase 3 trial were consistent with favorable results from previous Gimoti studies. In particular, there were no adverse events of special interest, such as the central nervous system (CNS) effects observed with oral and parenteral formulations of metoclopramide. Based on recent FDA discussions, these data are anticipated to be submitted as part of a new drug application (NDA) for Gimoti.

"As we prepare our 505(b)(2) NDA for Gimoti, including a comparative exposure pharmacokinetic (PK) study, acceptance of our Phase 3 data as a late breaker for poster presentation at DDW 2017 provided another opportunity for us to share the clinical importance of metoclopramide nasal spray for women suffering from the symptoms of moderate to severe diabetic gastroparesis," stated Marilyn R. Carlson, DMD, MD, Chief Medical Officer. "We are very pleased that DDW accepted this data for presentation as we believe it is among the most up-to-the-minute and novel GI developments that will impact research and the care of patients."

The Phase 3 trial was a U.S. multicenter, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of Gimoti compared to placebo in adult female subjects with symptomatic diabetic gastroparesis and delayed gastric emptying. Eligible patients were randomized 1:1 between Gimoti or placebo administered as a single nasal spray four times daily; 30 minutes before meals and at bedtime for a total of four weeks. The primary endpoint was the change in the total symptom score from baseline to week four. The trial data was not statistically significant in the ITT group (N=205, p=0.881).

The authors of the presentation were Richard W. McCallum, MD, Texas Tech University Health Sciences Center, El Paso, Texas; Ronnie Fass, MD, Case Western Reserve University, Cleveland, Ohio; Bal R. Bhandari, MD, Delta Research Partners, Monroe, Louisiana; Marilyn R. Carlson, DMD, MD and Wayne M. Alves, PhD, Evoke Pharma, Inc., Solana Beach, California.

The data poster is available on the investors section of the Company's website, http://investor.evokepharma.com/, under the "Presentations and Posters" section.

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 Gimoti, 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. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal 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: Evoke's plans to present at DDW and discuss the data from its Phase 3 trial for Gimoti; the benefits Gimoti may have for patients with moderate to severe gastroparesis symptoms; the timing of any 505(b) (2) NDA submission for Gimoti with the FDA; the Company's plans to conduct the comparative exposure PK study and include the results in the Gimoti NDA; and the utility of the Gimoti data to scientists and clinicians at DDW. 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 risks and uncertainties inherent in Evoke's business, including, without limitation: risks associated with successfully commencing and receiving favorable results from the planned PK trial; later developments with the FDA that may be inconsistent with the already completed pre- NDA meetings, including inconsistent conclusions reflected in the official meeting minutes from the FDA; the inherent risks of clinical development of Gimoti, in particular since the Phase 3 trial failed to reach its primary endpoint in the ITT population; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing new formulations of Gimoti for use in the PK trial; Evoke's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK trial and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; 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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