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Evoke Provides Additional Data Demonstrating Statistically Significant Benefit for Gimoti in Moderate to Severe Patients in Phase 3 Diabetic Gastroparesis Trial

Nausea and abdominal pain symptoms significantly reduced in patients with higher symptom severity

SOLANA BEACH, CA, Jan. 04, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today provided additional data from the Phase 3 trial of Gimoti, its nasal delivery of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Although the Phase 3 trial failed to reach its primary endpoint, data also demonstrated that patients with moderate to severe symptoms, which included 105 of the 205 patients (51%) enrolled in the study, responded statistically significantly better when treated with Gimoti than those treated with placebo at multiple time points in the Intent-to-Treat (ITT) and Per Protocol populations (Table 1). There were also clinically and statistically significant improvements in nausea and abdominal pain, which are two of the more severe and debilitating symptoms of gastroparesis (Table 2).

These results in patients with moderate to severe symptoms are 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for the treatment of gastroparesis issued in July 2015 (Gastroparesis: Clinical Evaluation of Drugs for Treatment, Draft Guidance). This guidance represents the FDA's current thinking on the evaluation of treatments for gastroparesis and states that trials should enroll patients with higher symptom severity in order to optimize the ability to demonstrate a treatment effect. At the time this guidance was issued, the Company's Phase 3 study, designed to include patients with a range of symptom severity, had been actively enrolling for more than a year. The overall efficacy results were not significant, due in large part to the milder patients who responded to placebo. Importantly, the efficacy of Gimoti was demonstrated in the subset of patients described in the guidance, i.e., those who entered the study with higher symptom severity.

Phase 3 safety data revealed no significant adverse effects and 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 metoclopramide (Table 3). There have been no reports of tardive dyskinesia among the 1,311 exposed healthy volunteers and patients over the clinical development program.

"As our discussions with the FDA progressed over the past few months, we have continued to analyze data from our Phase 3 trial of Gimoti. These additional analyses have provided us with important insights regarding the efficacy of Gimoti in patients with varying levels of symptom severity, despite not reaching the trial's primary endpoint," stated Dave Gonyer, R.Ph., President and CEO. "Among the more significant outcomes from these analyses was the statistically significant and clinically meaningful improvement in symptom scores in moderate and severe patients which consisted of a large portion of the overall study population. In this group, those treated with Gimoti reported significantly better results than those who received placebo with benefits seen as early as study week one. It is also important to note that nausea and abdominal pain, two of the more severe and common symptoms of gastroparesis, showed the most improvement in patients receiving Gimoti. These symptom benefits were also observed in our Phase 2B trial."

"Patients suffering from moderate to severe flares of gastroparesis who do not respond to treatment with oral metoclopramide often require hospitalization, which creates a significant market opportunity. Gimoti offers patients an outpatient option that can be delivered consistently even during symptom flares characterized by nausea and vomiting. The consistently favorable safety profile of Gimoti among patients treated in our clinical trials and the benefits we have demonstrated, indicate that Gimoti can have a positive impact on the lives of these patients used prior to, and outside of, a hospital setting," concluded Mr. Gonyer.

The 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 and was not statistically significant in the ITT group (N=205, p=0.881). Safety and

additional efficacy results are summarized in the tables below.

Table 1: Phase 3 Estimated Mean Change from Baseline in Mean Daily GSA Total Scores: Moderate to Severe Study Populations

Population	Time Period	Placebo[1]	Gimoti[1]	*p*-value[2]
		(N = 53)	**(N = 52)**	
	Week 1	-0.387	-0.588	**0.036**
	Week 2	-0.614	-0.950	**0.025**
Intent-to-Treat	Week 3	-0.749	-1.096	**0.039**
	Week 4	-0.856	-1.220	0.085*
		(N = 40)	**(N = 38)**	
	Week 1	-0.362	-0.623	**0.019**
	Week 2	-0.625	-1.040	**0.015**
Per Protocol	Week 3	-0.714	-1.286	**0.003**
	Week 4	-0.841	-1.373	**0.014**

Table 2: Mean Change from Baseline in Mean Daily Nausea and Upper Abdominal Pain Score in Intent-to-Treat Population with Moderate to Severe Symptoms

Symptom	Time Period	Placebo[1] (N = 53)	Gimoti[1] (N = 52)	*p*-value[2]
Nausea	Week 1	-0.370	-0.859	**0.001**
	Week 2	-0.696	-1.149	**0.032***
	Week 3	-0.818	-1.242	**0.043**
	Week 4	-0.905	-1.404	**0.027**
Upper Abdominal Pain	Week 1	-0.394	-0.641	**0.025**
	Week 2	-0.554	-0.990	**0.016**
	Week 3	-0.690	-1.194	**0.008**
	Week 4	-0.791	-1.218	**0.047**

[1] LSMean from ANCOVA

[2] *p*-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the *p*-value was obtained from a rank ANCOVA test and denoted with an *.

Table 3: Selected Treatment-Emergent Adverse Events Reported by More than 2 Subjects in Any Treatment Group

Adverse Event	Placebo (N = 103)	Gimoti (N = 102)
Headache	7 (7%)	5 (5%)
Nasal discomfort	4 (4%)	1 (1%)
Epistaxis	2 (2%)	1 (1%)
Fatigue	1 (1%)	2 (2%)

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," , or 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 potential for Gimoti to have a positive impact on the lives of the patients who use it. 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: the data reported only includes a portion of the patients in the Phase 3 clinical trial of Gimoti and that the Phase 3 trial failed to reach its primary endpoint; risks associated with successfully commencing and receiving favorable results from the planned pharmacokinetic trial; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings, including that the FDA will not accept selected data from our Phase 3 clinical trial; the FDA may change its recommendations regarding evaluation of drugs for the treatment of gastroparesis; the inherent risks of clinical development of Gimoti; 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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