



October 23, 2017

## **Evoke Pharma Announces Positive Topline Results from Comparative Exposure Pharmacokinetic Study for Gimoti™**

### **505(b)(2) NDA on track for FDA submission in Q1 2018**

SOLANA BEACH, Calif., Oct. 23, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced positive topline results from the Company's comparative exposure pharmacokinetic (PK) study. The trial was designed to demonstrate that a proposed dose of Gimoti, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis, has similar systemic exposure to that of the referenced listed drug (RLD), Reglan Tablets. Based on the results, the Company will submit a 505(b)(2) New Drug Application (NDA) with a selected Gimoti dose to the U.S. Food and Drug Administration (FDA) in the first quarter of 2018.

The PK study was an open label, 4-way crossover and enrolled 108 male and female healthy volunteers who were each to receive one Reglan Tablet dose and three different doses of Gimoti in a random sequence. Following discussions at pre-NDA meetings with FDA, Evoke planned to select a Gimoti dose based on criteria that includes a 90% confidence interval for the ratio of area under the plasma concentration curve (AUC) falling within the bioequivalence range of 80-125% of the RLD. Two of the three doses tested met the selection criteria. The maximum observed plasma concentration ( $C_{max}$ ) for Gimoti was slightly lower than the bioequivalence range, which had been previously discussed with FDA as a likely outcome given the different route of administration and prior Gimoti PK study results. Additionally, data showed the AUC and  $C_{max}$  increased in a dose related manner across all three strengths tested. Relative to safety, all Gimoti doses were well-tolerated with no clinically significant adverse events reported following any of the doses.

"We are very pleased this study has met our objective of demonstrating bioequivalence on the measure of AUC to identify a Gimoti dose," said Dave Gonyer, Evoke Pharma's CEO. Mr. Gonyer continued, "In the first quarter of 2018, we will submit the NDA with these PK data, as well as safety and efficacy data from five prior Evoke clinical studies in healthy volunteers and patients with diabetic gastroparesis. We believe Gimoti has the potential to become the new standard of care for patients suffering from this debilitating disease and we look forward to providing further updates regarding the NDA as we move quickly toward submission."

### **About Gimoti**

Gimoti has been in development for over a decade to provide a non-oral, outpatient alternative to treat the symptoms of gastroparesis in patients. Non-oral treatment is optimal as gastroparesis, also known as gastric stasis, results in erratic absorption of oral medications. Metoclopramide, the active ingredient in Gimoti, has been approved as a tablet and an injection to treat gastroparesis in the US since 1980. Approximately 4 million prescriptions of oral metoclopramide are written per year in the US.

Evoke has conducted a number of clinical trials that will be submitted with data from the comparative exposure pharmacokinetic trial. These include a Phase 1 PK bioavailability study, a Phase 1 thorough ECG cardiac safety trial, a Phase 2b efficacy and safety trial, a Phase 3 efficacy and safety trial in women and a companion efficacy and safety trial in men.

### **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 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](http://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 beliefs about the study data, including that the objective of the PK study has been met on the measure of AUC and that the topline results demonstrate comparable bioequivalence between the oral Reglan Tablets and Gimoti's nasal delivery; beliefs that the AUC measurement is the most clinically relevant PK parameter for this study; the timing of the submission of the NDA to the FDA; Evoke's expectation that the PK trial will be the final clinical trial for Gimoti prior to NDA submission; Evoke's belief that Gimoti may become the new standard of care for patients suffering from gastroparesis; and Evoke's belief that there is a large unmet need for an effective treatment for diabetic gastroparesis. 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 topline data Evoke has reported from the PK study is based on preliminary analysis of key data, and such data may change following a more comprehensive review of the data related to the PK study and such topline data may not accurately reflect the complete results of the study, and the FDA may not agree with Evoke's interpretation of such results, including risks associated with  $C_{max}$  falling below the bioequivalence range; 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; risks that the FDA may require additional efficacy or safety studies prior to submission or approval of the NDA; 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; Evoke's dependence on third parties for the manufacture of Gimoti as well as the submission of the NDA; Evoke may require additional funding to submit the NDA and conduct any additionally required studies, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; 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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