October 27, 2017

Evoke Pharma Announces Conference Call to Review the Successful Results of Comparative Exposure Pharmacokinetic Study for Gimoti™

Call Scheduled for October 31st at 9am ET

SOLANA BEACH, Calif., Oct. 27, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, recently announced positive topline results from the Company's comparative exposure pharmacokinetic (PK) study for Gimoti, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis. The trial demonstrated that more than one of the tested doses of Gimoti had similar systemic exposure to that of the referenced listed drug (RLD), Reglan Tablets. Based on these results, the Company will select a Gimoti dose and submit a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the first quarter of 2018.

"The recently completed PK study was successful and achieved its objective of identifying a Gimoti dose for submission in the 505(b)(2) NDA. We look forward to the opportunity provide more clarity surrounding questions the company has received based on the recent data release," stated Dave Gonyer, President and CEO. "The results of this study were positive and an incredibly important milestone for the company and the development of Gimoti."

The conference call will focus on the topline results of the PK study and the Company's regulatory strategy for a 505(b)(2) NDA for Gimoti including:

- FDA discussions and feedback which allow for the selection of a Gimoti dose based on area under the plasma concentration curve (AUC) within the bioequivalence range of 80-125% of the RLD.
- Maximum observed plasma concentration (C_{max}) was anticipated to be lower than the RLD and results were in line with expectations. The Company discussed this with FDA during their review of the protocol and prior to study initiation.
- Regulations for innovator products such as Gimoti (21 CFR Part 320.23 Bioavailability and Bioequivalence Requirements) that allow for variations in rate of absorption (C_{max}).
- Two of three Gimoti doses achieved the required AUC range, even though only one was needed to meet the criteria.

The company plans to submit a 505(b)(2) NDA for Gimoti in the first quarter of 2018. The NDA will contain these PK data as well as safety and efficacy data from the additional five previously completed Gimoti studies in healthy volunteers and patients with diabetic gastroparesis.

Evoke will host a conference call and webcast at 9:00 am ET on Tuesday, October 31, 2017.

To access the conference call, participants should dial 1-877-407-0789 (United States) or 1-201-689-8562 (International) and mention Evoke Pharma. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.evokepharma.com.

After the live webcast, the event will be archived on Evoke's website for one year. In addition, a telephonic replay of the call will be available until November 7, 2017. The replay can be accessed by dialing 1-844-512-2921 (United States) or 1-412-317-6671 (International) with confirmation code 13672987.

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 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 PK study was successful and the objective of the PK study has been met on the measure of AUC; the timing of the submission of the NDA to FDA and that such submission will be in accordance with FDA regulations for innovator products; Evoke's beliefs as to what is required by FDA to allow an NDA submission; 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 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 FDA that may be inconsistent with the already completed pre-NDA meetings, including inconsistent conclusions reflected in the official meeting minutes from FDA; risks that 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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