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Evoke Pharma Completes Dosing for Gimoti™ Comparative Exposure Pharmacokinetic Study

Data expected in Q4 2017 followed by a 505(b)(2) NDA submission in late 2017/early 2018

SOLANA BEACH, Calif., Sept. 12, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has completed subject dosing for a comparative exposure pharmacokinetic (PK) study comparing Gimoti to the listed drug, Reglan® Tablets. Gimoti is the company's lead drug candidate for the treatment of symptoms associated with acute and recurrent diabetic gastroparesis. The company expects to announce data from the trial in the fourth quarter of 2017, followed by a 505(b)(2) New Drug Application (NDA) submission by the end of 2017 or early 2018.

The study was designed to demonstrate that a proposed dose of Gimoti has a similar systemic exposure to that of the listed drug, Reglan Tablets. The study, conducted at a single study site, is a single dose, 4-way crossover design that enrolled approximately 100 healthy volunteers who each received Reglan Tablets and three different doses of Gimoti in a random sequence.

"We believe the completion of this comparative exposure PK study will mark the final clinical milestone for our development program of Gimoti." commented Dave Gonyer, R.Ph., President and CEO. "As we have mentioned in the past and as we have discussed with the U.S. Food and Drug Administration (FDA) in our previous meetings, the PK study results will be used as part of an NDA submission for Gimoti along with considerable data we've generated over the last decade of development. We remain confident that Gimoti, our nasal formulation of metoclopramide, has the potential to improve the lives of those suffering from gastroparesis, and we look forward to providing further updates on our progress in the coming months."

As a reminder, Dave Gonyer will be presenting at the 19th Annual Rodman & Renshaw Global Investment Conference today, September 12, 2017 at the Lotte New York Palace Hotel in New York City. The presentation will begin at 10:00 a.m. EDT and will take place in the Louis Room.

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 plans to include the PK data in the 505(b)(2) NDA for Gimoti; the timing of announcement of the results of the PK trial and 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; 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: risks associated with successfully conducting, completing and receiving favorable results from the 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; 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 submission of the NDA; Evoke's dependence on Spaulding Clinical Research to conduct 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; 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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