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Evoke Pharma Initiates Comparative Exposure Pharmacokinetic Study for Gimoti™

Expected to be final clinical trial prior to 505(b)(2) NDA submission

SOLANA BEACH, Calif., Aug. 14, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the initiation of its comparative exposure pharmacokinetic (PK) trial for Gimoti, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The study is designed to demonstrate that the proposed dose of Gimoti has similar systemic exposure to that of the listed drug, Reglan® Tablets, and PK data will be part of the basis for the Company's planned 505(b)(2) new drug application (NDA) to the U.S. Food and Drug Administration (FDA). The study is a single dose, crossover design in which approximately 100 healthy volunteers will receive Reglan Tablets and three different doses of Gimoti. The study will be conducted by Spaulding Clinical Research, a clinical research organization (CRO) that successfully completed the Company's thorough ECG trial for Gimoti in 2014. The Company expects to complete the analysis of the trial data and announce results in the fourth quarter of 2017, followed by a potential NDA submission in late 2017 or early 2018.

"The initiation of this PK study follows the positive guidance from FDA in December 2016 that this is an acceptable pathway toward a 505(b)(2) NDA submission. At our Type A meeting with FDA in March 2017, we also reached agreement on the study design," commented Marilyn R. Carlson, DMD, MD, RAC, and Chief Medical Officer of Evoke. "We have spent the last several months finalizing the protocol, contracting with key vendors, and securing study drugs for what we believe to be the final clinical trial for Gimoti. We are confident in the capabilities of Spaulding, a CRO with nasal spray experience that we have worked with in the past, to execute on a successful trial for Gimoti. Upon completion of the PK study, we intend to work quickly to complete the NDA submission. There is a large unmet need for an effective treatment for diabetic gastroparesis and we look forward to submitting our NDA for Gimoti."

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 Spaulding Clinical Research will complete the study; 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 initiating, conducting 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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