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Evoke Receives Positive NDA Submission Guidance from US FDA for Gimoti

Healthy volunteer bridging study to oral metoclopramide to be completed and submitted in NDA with existing safety and efficacy data

SOLANA BEACH, Calif., Dec. 15, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced positive guidance from a recent second pre-NDA (New Drug Application) meeting to discuss clinical data for inclusion in a 505(b)(2) NDA for Gimoti™ with the US Food and Drug Administration (FDA). This pre-NDA meeting was the second for Gimoti™, Evoke's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Following discussion of the clinical data Evoke provided for this meeting, the FDA agreed that demonstration of equivalent exposure to the listed drug (Reglan® 10 mg Tablets) in a healthy volunteer pharmacokinetic (PK) trial could serve as a portion of an NDA for Gimoti. Upon demonstration of appropriate exposure in a PK trial, Evoke will submit the PK data and prior clinical studies to the Agency for review in the Gimoti NDA. The FDA agreed that no new efficacy or safety study would be required, if bioequivalence criteria were met. During NDA review and labeling negotiations, safety and efficacy data from completed Gimoti studies, including the thorough ECG study, may be used to support information included in the Gimoti label.

For this pre-NDA meeting, the Company provided Phase 3 data that showed statistically significant efficacy compared to placebo for patients with moderate to severe symptoms at baseline in a post-hoc analysis. The moderate to severe population consisted of more than half of the 205 women participating in the trial. The benefit for Gimoti compared to placebo in this population was demonstrated at various time points in the intent-to-treat, per protocol, and completer populations. In addition, favorable safety data from the placebo-controlled studies in diabetic gastroparesis patients and the studies in healthy volunteer will support the planned Gimoti NDA.

In the first pre-NDA meeting with the FDA held in August 2016, Evoke confirmed various regulatory, chemistry, manufacturing, and control (CMC), and non-clinical requirements for the Company's potential NDA submission.

"Our meeting with the FDA represents another positive step forward for our clinical program and our path to an NDA submission," stated, Dave Gonyer, R. Ph., President and CEO. "With the FDA's guidance, Evoke intends to complete an additional pharmacokinetic trial and file an NDA, without the need for additional efficacy studies. Given these two positive pre-NDA meetings, we believe the Company is well-positioned to move forward to an NDA and potential approval of Gimoti for diabetic gastroparesis in adult women."

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," "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 submission of an NDA for Gimoti based on a new PK trial without the need for additional efficacy studies and the FDA's agreement on such approach, and Evoke's plans to conduct the PK trial and submit the NDA and potentially receive regulatory approval of Gimoti. 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: risks associated with successfully commencing and receiving favorable results from the planned 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 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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