Evoke Announces Discovery of Sex-Based Pharmacokinetic Differences for Gimoti™

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Recent Pre-NDA Meeting Provided Guidance on Female Only NDA Filing Strategy and Post-Approval Safety Study

SOLANA BEACH, Calif., Feb. 15, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) d--iseases, today announced additional findings from its comparative exposure pharmacokinetic (PK) trial for Gimoti™, the Company's novel nasal spray delivery of metoclopramide for the treatment of symptoms associated with gastroparesis. Further analysis of the PK data by sex revealed statistically significant differences in exposure between women and men given the same metoclopramide dose (nasal and oral). The Company has filed new patent applications related to the discovery.

In December 2016, the Company announced the U.S. Food and Drug Administration (FDA) had agreed that a PK trial could serve as a basis for submission of a 505(b)(2) new drug application (NDA), along with efficacy and safety data from previous clinical trials. Recently, the Company announced that the comparative exposure PK trial met bioequivalence criteria for total exposure, or area under the curve (AUC). After additional analysis of the PK data, statistically significantly lower AUC's were found in men compared to women and was not explicitly attributable to the subject's body mass index (BMI) or weight. Similar differences in the metoclopramide PK parameters between women and men, regardless of the route of administration (nasal, oral and IV), were also found in a retrospective analysis of data from an earlier PK study conducted by the Company.

In the most recent comparative exposure PK trial, measurements for women independently met bioequivalence criteria for $AUC_{0\text{-}inf}$ and $AUC_{0\text{-}t}$ at the tested Gimoti dose to be proposed in the NDA. The Company plans to submit its NDA for a female-only indication based on a dose in women with equivalent exposure to Reglan Tablets (the reference listed drug) and will submit supporting efficacy and safety data from its Phase 2b and Phase 3 trials, specifically for women, at doses similar or lower than the dose to be proposed in the NDA.

In parallel, the Company recently held an additional pre-NDA meeting with FDA to discuss and clarify the Agency's expectations of items being prepared for inclusion in the NDA for Gimoti. The planned NDA will include the Company's proposal for a risk management strategy and a post-approval safety study that will be designed to confirm prior safety findings and rule-out possible differences with side effects compared to the Reglan oral tablet over 8 weeks. The Company expects to discuss the details of the post-marketing safety trial with FDA during the NDA review process. With the new sex-based findings, and to fully incorporate the feedback received by FDA at the pre-NDA meeting, the Company now expects to file the Gimoti NDA in the second quarter of 2018.

"The discovery of a sex-based PK exposure differential for metoclopramide and Gimoti is exciting, as we believe the exposure differences may explain the efficacy results seen in our previous clinical trials where Gimoti reduced symptoms of gastroparesis in women, but not men," commented Dave Gonyer, President and CEO. "We hope this finding can help with future treatment decisions for those who suffer from symptoms of gastroparesis."

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: Evoke's plans to pursue approval of Gimoti in adult women with diabetic gastroparesis; Evoke's belief that the sex-based PK differences are important to gastroparesis treatment; Evoke's plans with respect to the content of the NDA submission, including a proposed post-marketing risk management strategy and safety trial; and the timing of the NDA submission. 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: the FDA may disagree that the existing safety database and efficacy data is sufficient to allow an NDA submission and approval, including risks associated with C_{max} falling below the bioequivalence range in the comparative exposure PK trial and the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration; the FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; the FDA may require additional evidence of sex-based PK differences of Gimoti before making a final decision on Gimoti; risks associated with the size, cost and duration of a post-marketing safety trials; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; 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 will require substantial additional funding to conduct any new trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to obtain, maintain and enforce intellectual property rights; 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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