April 4, 2017

Positive Type A Meeting with FDA Confirms Acceptability of Evoke Pharma's Proposed Comparative Exposure PK Trial for Gimoti NDA

SOLANA BEACH, Calif., April 04, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the Company recently completed a positive Type A meeting with the U.S. Food and Drug Administration (FDA) to finalize the design of the pivotal comparative exposure pharmacokinetic (PK) trial and to reach agreement on additional aspects of the Chemistry, Manufacturing & Controls (CMC) section of the New Drug Application (NDA) for Gimoti™, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

During a pre-NDA meeting announced in December 2016, FDA agreed with Evoke that a comparative exposure PK trial to demonstrate the bioequivalence of Gimoti in healthy volunteers could serve as the basis for a 505(b)(2) NDA submission for Gimoti. FDA recommended that Evoke submit the trial protocol for review prior to initiating the study, which Evoke provided in early March 2017. The Type A meeting was granted to allow comment and discussion with FDA regarding the structure, population and overall design of the PK trial. After discussing the protocol design with FDA, Evoke has agreed with their comments and plans to incorporate the Agency's recommendations in the final protocol.

The pivotal comparative exposure PK trial will be conducted in healthy volunteers to demonstrate the bioequivalence of Gimoti to the reference listed drug, Reglan® Tablets. The Company is preparing to execute the trial and expects to have results in the second half of 2017. Additionally, agreement was received on items related to the CMC section of the NDA during the Type A meeting. The Company believes it will be able to submit the NDA for Gimoti by late 2017 or early 2018.

"We are pleased to have FDA's input on the protocol for our comparative exposure PK trial, which, along with collecting CMC data associated with the trial, we believe are the last key items to be completed prior to submission of the NDA for Gimoti," said Dave Gonyer, R.Ph., President and CEO of Evoke. "In our communications and discussions with FDA, the Agency provided advice on the proposed design of the study, which helps clear the path to move ahead with our timeline as scheduled. We remain confident in our ability to continue to execute on the milestones that we have outlined to bring Gimoti to commercialization."

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 plans to incorporate the Agency's recommendations in the final trial protocol; the trial being the last outstanding item needed prior to submission of the NDA for Gimoti; and Evoke's plans to conduct and complete the PK trial and submit the NDA and the timing thereof. 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 trial; later developments with FDA that may be inconsistent with the already completed pre-new drug application (NDA) and Type A 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; 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;; 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.

Investor Contact:
The Ruth Group
Tram Bui
Tel: 646-536-7035
tbui@theruthgroup.com