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Evoke Pharma Announces Collaboration with Spaulding Clinical Research for the Gimoti Comparative Exposure Pharmacokinetic Trial

SOLANA BEACH, Calif., April 18, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the Company has reached an agreement to work in partnership with Spaulding Clinical Research for its planned comparative exposure pharmacokinetic (PK) trial for its lead product candidate, Gimoti™, a patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. The pivotal PK trial conducted in healthy volunteers is designed to establish bioequivalence with the listed drug, Reglan® Tablets, and may serve as a basis for the 505(b)(2) new drug application (NDA) planned for submission to the Food and Drug Administration (FDA).

This PK trial follows recent communications with FDA regarding the final clinical development steps for the NDA submission. The Company held a face-to-face pre-NDA meeting with FDA in December 2016 to propose and discuss this PK trial and recently confirmed the final protocol design during a Type A Meeting with FDA last month. The Company engaged Spaulding to execute this trial and is now in the latter planning stages to initiate the trial.

"We are very pleased to continue our relationship with Spaulding Clinical for our PK trial for Gimoti and remain on schedule to initiate the trial in the second half of the year. We believe a successful PK trial will conclude our clinical development work for Gimoti and may provide the final data needed to complete the 505(b)(2) NDA," said Marilyn R. Carlson, DMD, MD, RAC, Chief Medical Officer of Evoke. "Previously, the Spaulding team successfully initiated and completed our Gimoti thorough ECG trial in 2014. We look forward to completing the PK trial in the second half of 2017 with the NDA submission for Gimoti to follow in late 2017 or early 2018."

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.

Spaulding Clinical Research, LLC is a global clinical research organization providing a range of Phase 1 — 4 drug development services to the biotechnology and pharmaceutical industries. Spaulding Clinical Research operates a 200-bed Clinical Pharmacology Unit, Cardiac Core Laboratory and provides full Biometrics/Scientific Affairs services. The company was founded in 2007 and is based in West Bend, Wisconsin.

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 launch the PK trial with Spaulding Clinical; the possibility that the PK trial may provide the final data necessary to complete the NDA for Gimoti; the timing of the commencement and completion of the PK trial and the timing of the NDA submission, if any, for Gimoti; and the benefits Gimoti may have for patients with moderate to severe gastroparesis symptoms. 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; 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 Evoke's dependence on Spaulding Clinical for 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.

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