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Evoke Receives Favorable Response From U.S. Food and Drug Administration Regarding Pediatric Study Plan for EVK-001

SOLANA BEACH, Calif., Aug. 18, 2015 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the receipt of a letter from the U.S. Food and Drug Administration (FDA) indicating the agency's concurrence with the Company's proposed pediatric study plan for EVK-001.

Pursuant to the terms of the letter, the FDA has accepted Evoke's EVK-001 pediatric study plan, which included a request for a full waiver of the requirement to conduct pediatric studies on the basis that diabetic gastroparesis is an adult disease. The Company expects that the pediatric study plan will be included in the Company's anticipated New Drug Application (NDA) filing with the FDA.

"We are pleased that the FDA had a favorable response to our proposed pediatric study plan in which we have proposed a full waiver for pediatric testing of EVK-001 in all pediatric age groups," stated Marilyn Carlson, D.M.D, M.D., RAC, Chief Medical Officer of the Company. Dr. Carlson continued, "Having received this agreement prior to data from our ongoing Phase 3 clinical trial will allow us to focus on study completion and NDA submission in a timely manner."

"The agreed upon pediatric study plan is another positive step forward for the Company from a clinical and regulatory perspective," stated Mr. Gonyer, R.Ph., President and Chief Executive Officer. "We believe that this agreement, along with the recent FDA guidance document that assists companies in the clinical development of drugs for the treatment of gastroparesis, specifically trial design and clinical endpoint evaluation, are consistent with the advice given by the FDA on the design of our current Phase 3 clinical development program. We continue to progress toward an NDA filing and commercialization of EVK-001 with the hope of providing a better treatment option for patients with diabetic 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 EVK-001, 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. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through intranasal 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 timing and completion of Evoke's ongoing Phase 3 clinical trial of EVK-001 and the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis. 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 risk and uncertainties inherent in Evoke's business, including, without limitation: Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the FDA's letter regarding Evoke's pediatric study plan is not binding on the FDA, and the FDA may revise its indications regarding such plan; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; the inherent risks of clinical development of EVK-001, including continued delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke will require substantial additional funding to complete the Phase 3 clinical

trial and potentially commercialize EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; 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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