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Evoke Pharma Study Reports Positive Results of Metoclopramide Nasal Spray for Gastroparesis in Diabetics

SAN DIEGO, Jan. 22, 2014 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the publication of a study that found intranasal delivery of metoclopramide to be more effective in managing symptoms of diabetic gastroparesis compared to the marketed oral tablet formulation of metoclopramide.

The Phase 2b study, which was published online ahead-of-print for an upcoming issue of *Neurogastroenterology & Motility*, enrolled 89 patients from six study sites throughout the United States. The multicenter, randomized, open-label, parallel design study was the first to compare the efficacy and safety of metoclopramide nasal spray to oral tablets in diabetic patients with symptoms of gastroparesis when dosed four times a day for 6 weeks.

Marilyn Carlson, D.M.D., M.D., RAC, Chief Medical Officer of Evoke, said, "It is intuitive that a nasal spray will have more reliable absorption than a tablet in patients with delayed gastric emptying. These data from symptomatic diabetic gastroparesis patients confirm that metoclopramide nasal spray is well-tolerated and can offer better symptom relief than a tablet in this population."

"We believe the results from our Phase 2b clinical trial validate our novel intranasal delivery system of metoclopramide (EVK-001) which will be evaluated soon in our upcoming Phase 3 clinical trial," said Dave Gonyer, R.Ph., President and Chief Executive Officer of Evoke. "There haven't been any new drugs for the management of symptoms associated with gastroparesis approved by the FDA since 1980, and there are very few drugs in clinical development for this debilitating diabetic complication."

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 diabetic 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.

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 negative 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 ability of a nasal spray to offer better symptom relief than a tablet in diabetic patients with symptoms of gastroparesis; the upcoming Phase 3 clinical trial; and the market opportunity for EVK-001. 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: the inherent risks of clinical development of EVK-001, including potential delays in enrollment and completion of clinical trials, including the planned Phase 3 trial; Evoke will require substantial additional funding, including potentially to complete the planned Phase 3 clinical trial of EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed; the results observed in the Phase 2b study may not be predictive of the safety and efficacy results in the planned Phase 3 clinical trial or any other future trial; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; competition from other pharmaceutical or biotechnology companies; 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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