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Evoke Pharma Reports Topline Results from EVK-001 Phase 3 Clinical Trial

SOLANA BEACH, Calif., July 18, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced topline results from its Phase 3 clinical trial of EVK-001 in female patients with symptomatic diabetic gastroparesis. In this study, EVK-001, the Company's patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women, did not achieve its primary endpoint of symptom improvement at Week 4.

Preliminary review of topline data across all study sites revealed similar improvement in the EVK-001 and placebo groups at Week 4 as measured by the total symptom score as well as the individual scores for each of the signs and symptoms, but these results were not consistent across the study sites. Further evaluation of topline data revealed diary data from 28 of 41 of the enrolling sites showed a statistically-significant benefit at Week 4 for EVK-001 ($p=0.006$) in contrast to results from the other 13 sites that showed statistically significant benefit for placebo ($p=0.002$). Once the complete datasets and PK data are available, additional analyses will be conducted to further understand the discrepant results.

Safety results were consistent with findings from previous EVK-001 studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by healthy volunteers and patients with diabetic gastroparesis. In this Phase 3 study, there were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving EVK-001.

The study was a U.S.-based, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics (PK) of EVK-001 in 205 adult female subjects with diabetic gastroparesis who received EVK-001 or placebo four times daily for four weeks. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary Patient Reported Outcome (PRO) instrument. The PRO was used to calculate a weekly score based on daily telephone diary entries by study subjects who reported the frequency and severity of their gastroparesis signs and symptoms.

"The topline results are unexpected and an anomaly, given that metoclopramide has been approved and used for treating diabetic gastroparesis for more than 35 years. Additionally, EVK-001 provides predictable absorption of metoclopramide as seen in our prior trials," stated Dave Gonyer, R.Ph., President and CEO. "We continue to believe that EVK-001 is a promising treatment option for patients who currently rely on oral drugs to treat their symptoms of gastroparesis. Our analysis will continue as the remainder of the data become available and an update will be provided when we have more clarity on our steps ahead."

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 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," "or 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 EVK-001 serving as an effective and promising treatment option for gastroparesis, the absorption of metoclopramide with EVK-001, and Evoke's plans to conduct additional analysis of the trial data and potential next steps for the Company. 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: additional analyses of data from the Phase 3 trial may produce negative or inconclusive results, or may be inconsistent with previously announced topline results; the inherent risks of clinical development of EVK-001; Evoke is entirely dependent on the success of EVK-001, and Evoke cannot be certain that it will be able to conduct additional trials of EVK-001 or obtain regulatory approval for EVK-001; Evoke will require substantial additional funding to continue to develop EVK-001, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke's ability to comply with the financial and other covenants under its loan and security agreement with Pacific Western Bank, which could result in an event of default and an acceleration of outstanding amounts owed under the loan; 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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