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Evoke Pharma Outlines Progress on Clinical Program

SOLANA BEACH, Calif., Feb. 2, 2015 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today provided an update on its clinical program for EVK-001, its novel metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women.

In December, the Company announced it completed a thorough electrocardiogram (ECG) study (Thorough QT study) which successfully met its primary endpoint. The study demonstrated EVK-001 did not increase the cardiac QT and corrected QT (QTc) interval at therapeutic and supratherapeutic doses. The completion of the Thorough QT study represented an important milestone for the Company, as it now has only one remaining study required for its EVK-001 NDA submission.

Evoke is currently enrolling its Phase 3 clinical trial investigating the use of EVK-001 in a multicenter, placebo-controlled, double-blind, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis. The trial is expected to enroll 200 subjects at sites across the United States. While the study is progressing according to plan at many of the clinical trial sites with previous gastroparesis study experience, overall enrollment has been slower than previously anticipated. To date, the trial has randomized 74 subjects. Although the trial sites have been screening significant numbers of subjects, patients with diabetic gastroparesis typically have symptoms that vary in timing and severity, unpredictable gastric emptying delays, and complex medical histories. This combination of factors creates a challenge for enrollment into diabetic gastroparesis trials. As a result, enrollment is projected to complete in the second half of the year. In response, Evoke has undertaken additional initiatives to increase enrollment to further assist clinical trial sites in the identification of eligible study subjects.

"As we work toward finalizing enrollment of our Phase 3 trial, we are identifying the appropriately qualified diabetic gastroparesis subjects in order to provide the most comprehensive data when filing our NDA," said Dave Gonyer, President and CEO of Evoke. "There is a significant market opportunity for a novel treatment for patients suffering from this disease, and we believe EVK-001 can provide these patients a level of therapy that the current standard of care cannot. We remain focused on the successful execution of this study and look forward to moving EVK-001 toward commercialization."

Evoke's cash position as of December 31, 2014 was $14.2 million which the Company believes will be sufficient to fund its operations through 2015.

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.

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 enrollment completion of Evoke's ongoing Phase 3 clinical trial of EVK-001, the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis and Evoke's completed and ongoing trials and studies serving as a basis for submission of an NDA and the sufficiency of Evoke's resources to fund operations through 2015. 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 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 may spend its available cash faster than it anticipates; 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; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; 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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