September 15, 2015

U.S. Food and Drug Administration's (FDA) Draft Guidance is Consistent With Evoke's Current Phase 3 Study Design and Endpoint for EVK-001

States Patients With Diabetic Gastroparesis May Have Unpredictable Gastric Emptying and Altered Absorption of Orally-Administered Hypoglycemic Drugs

SOLANA BEACH, Calif., Sept. 15, 2015 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that its Phase 3 clinical trial design for EVK-001 (metoclopramide nasal spray) is consistent with the FDA's recommendations in the recently released draft guidance entitled *Gastroparesis: Clinical Evaluation of Drugs for Treatment - Guidance for Industry* (Draft Guidance). The new Draft Guidance contains the FDA's current thinking on trial design and study endpoints for drug development in the treatment of gastroparesis.

"We are pleased to see the recommendations contained in the FDA's Draft Guidance on gastroparesis are consistent with the feedback we received from the FDA for our Phase 3 study of EVK-001, which gives us further confidence in the design of our ongoing study," said Dave Gonyer, R.Ph., President and CEO. "Our patented nasal delivery of metoclopramide for the treatment of symptoms associated with diabetic gastroparesis in women is one of only a few products in development for this disease. With a Phase 3 clinical trial design and endpoint that are consistent with the specific recommendations for protocol design, endpoint analysis and disease-specific concerns, we believe there is less regulatory risk with our development program for EVK-001 as it relates to this Draft Guidance."

"The recommendations in the Draft Guidance are in line with the feedback we received from the FDA during our end of phase 2 meetings regarding the design and plans for the EVK-001 Phase 3 study, which led to our selection of the primary endpoint in the study, which consists of a patient-reported outcome (PRO) instrument for gastroparesis symptoms," said Marilyn R. Carlson, D.M.D., M.D., RAC, Chief Medical Officer. "This Draft Guidance provides recommendations for the design and endpoints used in gastroparesis clinical trials and outlines the FDA's expectation that all sponsors will develop a *well-defined and reliable PRO instrument* consistent with a drug's mechanism of action for use as the primary efficacy assessment tool in their clinical trials."

Dr. Carlson continued, "We are further encouraged by specific statements made within the Draft Guidance that acknowledge patients with diabetic gastroparesis may have *unpredictable gastric emptying and altered absorption of orally-administered hypoglycemic drugs*. Importantly, we believe the FDA's statements highlight the need for non-oral drugs like EVK-001 to treat the symptoms of gastroparesis. We believe that our intranasal formulation of metoclopramide is the only non-oral and non-injectable product in development and, if approved, may have the distinct advantage of being on the market for several years as the only new treatment approved to address this debilitating disease in these patients with erratic gastric emptying."

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 potential for FDA

agreement with our trial design based on feedback we received date and the Draft Guidance; the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis; and the potential of EVK-001 being the only new treatment approved on the market for several years . 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; risks associated with changes in the Draft Guidance or in the FDA's view on the sufficiency of our trial design; risks that issues with future manufacturing production will arise, whether as a result of noncompliance with CMC requirements or otherwise; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development, manufacturing and supply of EVK-001, and Evoke's current lack of long-term commercial manufacturing agreements; 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; the ability of Evoke to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its product candidate and the ability to operate its business without infringing the intellectual property rights of others; 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.

CONTACT: Investor Contact:

The Ruth Group

David Burke

Tel: 646-536-7009

dburke@theruthgroup.com

Media Contact:

The Ruth Group

Kirsten Thomas

Tel: 646-536-7014

kthomas@theruthgroup.com

Source: Evoke Pharma