FDA Accepts Evoke Pharma's NDA Resubmission for Gimoti™

January 21, 2020

PDUFA Target Goal Date is June 19, 2020

SOLANA BEACH, Calif., Jan. 21, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on the development of drugs to treat gastrointestinal (GI) disorders and diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's resubmission of its 505(b)(2) New Drug Application (NDA) for Gimoti™, the Company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis.

A six-month period of review from the FDA's date of receipt has been assigned for the resubmitted NDA and the application has been assigned a new Prescription Drug User Fee Act (PDUFA) target goal date of June 19, 2020.

"We are pleased that FDA has accepted our NDA resubmission and look forward to working with the Agency throughout the review process toward a potential approval," commented Dave Gonyer, President and CEO. "We will now turn our focus to ensuring commercial readiness, as we believe physicians and patients are in urgent need of a new treatment option for the management of diabetic gastroparesis. We remain confident that Gimoti can help fill this unmet medical need and improve the quality of life for patients suffering from this disease."

About Gastroparesis

Gastroparesis is a debilitating, episodic condition that disproportionately affects adult women and is characterized by slow or delayed gastric emptying of the stomach's contents after meals, often resulting in flares of symptoms that include nausea, vomiting, abdominal pain and bloating. Vomiting and gastric emptying delays can cause unpredictable absorption of food and oral medications, which complicate glucose control and can lead to dehydration and malnutrition. These clinical manifestations of gastroparesis have the potential to render existing oral drug treatment options ineffective. If approved, Gimoti would be the first non-oral outpatient drug treatment for symptoms associated with acute and recurrent diabetic gastroparesis in adult women and would represent the first significant advancement in the treatment of gastroparesis in 40 years.

About Evoke Pharma, Inc.
Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal (GI) disorders and diseases. The Company is developing Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis.

Diabetic gastroparesis affects millions of patients worldwide and may result in serious digestive system symptoms, loss of glucose control, and systemic complications, such as dehydration and malnutrition. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Metoclopramide is currently available only in oral and injectable formulations and is the only drug currently approved in the United States to treat gastroparesis. 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 results of any decision regarding the NDA from the FDA, including whether FDA will act by the PDUFA target goal date; Evoke's belief that Gimoti, if approved, can fill an unmet medical need for the management of diabetic gastroparesis and improve the quality of life for patients suffering from the disease; and Evoke's plans to focus on commercial readiness. 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 risks and uncertainties inherent in Evoke's business, including, without limitation: the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; Evoke may be unable to timely and successfully address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti, including as a result of adverse findings from a root cause analysis or data from the newly manufactured product batches not fully addressing issues raised by the FDA in the CRL and type A meeting; FDA may not agree with Evoke's conclusion of the results from the manufacturing testing or the root cause analysis, or may require Evoke to conduct additional studies; further analysis of the manufacturing data; the FDA may later determine to hold an advisory committee meeting and risks associated therewith; the inherent risks of clinical development and regulatory approval of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the manufacturing data; Evoke is entirely dependent on the success of Gimoti; Evoke will require substantial additional funding to continue its operations into the second quarter of 2020, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; Evoke could face significant additional costs due to litigation or other events; Evoke's ability to maintain the continued listing of its common stock on the Nasdaq Capital Market; 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.

Investor Contact:
The Ruth Group
Tram Bui
Tel: 646-536-7035
tbui@theruthgroup.com

Source: Evoke Pharma, Inc.