Evoke Pharma's Gimoti™ NDA Accepted for FDA Review

August 16, 2018

April 1, 2019 PDUFA Target Goal Date

Gimoti Brand Name Conditionally Accepted

SOLANA BEACH, Calif., Aug. 16, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the Company's 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, has been accepted for review by the U.S. Food and Drug Administration (FDA).

In its Filing Communication/Day-74 letter, FDA stated that the NDA received on June 1, 2018, is sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act (PDUFA) of April 1, 2019. If approved, Gimoti will be the first new non-oral drug treatment option for diabetic gastroparesis in four decades.

"We are pleased with FDA's acceptance of our NDA for filing, which reaffirms our commitment to bringing this novel non-oral drug product to adult women who suffer from diabetic gastroparesis. We believe that Gimoti holds the potential to significantly improve the quality of life for these patients, particularly those who fail to achieve adequate relief from current oral therapy, and often face debilitating symptom flares of nausea, vomiting and abdominal pain," commented Dave Gonyer, President and CEO.

Additionally, the Day-74 letter did not indicate that FDA is planning to hold an advisory committee meeting to discuss the NDA.

In a separate written communication, the Agency responded to our NDA request for proprietary name review by conditionally accepting the proprietary brand name, Gimoti. This review and conditional acceptance validate that Gimoti is a proprietary name consistent with FDA's goal of preventing medication errors and potential harm to the public associated with product misidentification or confusion.

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 also potentially render existing oral drug treatment options ineffective. If approved, Gimoti would be the first non-oral 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 GI disorders and diseases. The Company is developing Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. 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 potential timing of FDA action on the NDA for Gimoti; Evoke's plans to work with the Agency during the NDA review process; the lack of any need for FDA to conduct an advisory committee meeting in connection with its NDA review; and the potential of Gimoti to significantly improve the quality of life for women suffering from gastroparesis. 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 FDA to delay the PDUFA target action date due to FDA's internal resource constraints or other reasons; FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by FDA in the Day-74 Letter such as, among others, C_{max} falling below the bioequivalence range in the comparative

exposure PK trial, the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration, the adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; later developments with FDA that may be inconsistent with the already completed pre-NDA meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; the possibility of FDA failing to finally approve Evoke's proposed proprietary name through the NDA review process; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti or that Evoke will successfully commercialize Gimoti; Evoke will require substantial additional funding to conduct any new trials required by FDA, and may be unable to raise capital when needed, including to fund ongoing operations; 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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Source: Evoke Pharma, Inc.