Evoke Pharma Receives Preliminary FDA Communication on Gimoti™ NDA

March 4, 2019

SOLANA BEACH Calif., March 04, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), today announced the receipt of a multi-disciplinary review (DR) letter from the U.S. Food and Drug Administration (FDA) in association with the Gimoti 505(b)(2) New Drug Application (NDA). A DR letter is used by the FDA to convey preliminary thoughts on deficiencies identified during the initial stage of NDA review.

The letter described concerns in three sections of the NDA: Chemistry (combination product quality control and reproducibility specific to the commercially available sprayer device used with Gimoti); Clinical (lack of adequate information to support sex-based efficacy differences); and Clinical Pharmacology (maximum concentration (C_{max}) not within the parameters for bioequivalence for abbreviated NDAs). Although a DR letter reflects preliminary comments that are subject to change and does not reflect a final FDA decision on the NDA, approval of Gimoti by the PDUFA date of April 1, 2019 is uncertain given the letter.

The Company plans to respond to the deficiencies raised in the DR letter to allow time for potential FDA review prior to the PDUFA date.

"We were disappointed by this FDA notification and are in the process of evaluating and addressing FDA's comments. We remain focused on seeking approval for Gimoti to provide patients with an effective treatment that bypasses the stomach where oral medications are known to be erratically absorbed," said Dave Gonyer, CEO. "Predictably delivered therapeutic options for patients that suffer from gastroparesis remains of high interest to the Company and an important need for physicians and patients that suffer from gastroparesis."

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 Gastrointestinal (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 and potential approval; and Evoke's plans to respond to and address the deficiencies raised in the DR letter, and the potential for the FDA to review such responses prior to the PDUFA date. 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: Evoke may be unable to timely respond and successfully address the concerns raised by the DR letter; the FDA may not be able to consider Evoke's response before it takes final action on the NDA; the increased risk of the FDA issuing a Complete Response Letter (CRL) based on the deficiencies raised in the DR letter or other issues identified by the FDA as it completes its review of the NDA; the potential delay in the PDUFA target action date; the inherent risks of clinical development of Gimoti; Evoke could face significant additional costs due to additional regulatory requests, litigation or other events; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti; Evoke will require substantial additional funding to address any deficiencies raised in a potential CRL, and may be unable to raise capital or obtain funds 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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