Evoke Receives FDA Conditional Acceptance of Gimoti Brand Name Following NDA Resubmission

May 20, 2020

SOLANA BEACH, Calif., May 20, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proprietary brand name, “Gimoti,” for the Company’s nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis as resubmitted in the 505(b)(2) New Drug Application (NDA).

The name Gimoti (pronounced “jye-MOH-tee”) was developed in compliance with FDA’s *Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names*. Based on the development program, which included research with physicians and pharmacists, as well as an international name assessment, the Company believes Gimoti is a proprietary name with strong marketing potential that is also consistent with FDA’s goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use.

“Receipt of conditional proprietary brand name approval further supports our commercialization strategy,” said Dave Gonyer, R.Ph., President and CEO. “Gimoti’s nasal spray delivery is designed to facilitate drug absorption by allowing Gimoti to bypass the dysfunctional GI track in patients with this disease. We continue to believe Gimoti, if approved, will provide an important new product that has the potential to help treat patients suffering from gastroparesis.”

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 GI symptoms as well as other systemic complications. 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: whether conditional proprietary brand name approval will support Evoke’s commercialization strategy, if Gimoti is approved; and potential FDA approval of the Gimoti NDA. 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 FDA may not approve the Gimoti NDA or give final approval of the Gimoti brand name; the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; FDA may not agree with Evoke's conclusion of the results from the manufacturing testing or the root cause analysis Evoke provided to address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti; the FDA may require Evoke to conduct additional studies; 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; 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.