Evoke Resubmits Gimoti™ New Drug Application to FDA

December 20, 2019

SOLANA BEACH, Calif., Dec. 20, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has resubmitted its 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Gimoti™, the company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis.

The NDA for Gimoti was resubmitted based on feedback received during the Type A meeting with FDA in July 2019. The meeting was held to obtain feedback and agreement on the items cited as deficiencies in the Complete Response Letter (CRL) issued by FDA in April 2019. In the CRL, FDA stated the NDA was not approvable as originally submitted and provided recommendations to address approvability issues related to clinical pharmacology and product quality/device quality.

Based on specific FDA feedback, in the resubmission Evoke has provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission includes an in-depth root cause analysis, and patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission includes 3-month stability data from commercial scale registration batches that met all product specifications and support the proposed acceptance criteria for performance characteristics and device quality control. Additionally, as requested by FDA, the resubmission includes data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications.

"We are very pleased to have been able to provide the information requested by FDA in the resubmission of the NDA for Gimoti," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. "If approved, we believe Gimoti has the potential to advance the treatment for gastroparesis treatment by delivering the drug nasally, to help avoid problems with GI absorption commonly seen in patients with 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 also potentially 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 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 Company's ability to address the issues raised by the FDA in its CRL regarding Gimoti, including by providing the information requested by FDA . 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 cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; Evoke may be unable to timely and successfully address the deficiencies raised in the CRL, 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 as part of the planned NDA resubmission altering the initial conclusions; the inherent risks of clinical development 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 beyond 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.

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