Evoke Pharma Receives Complete Response Letter and Recommendations to Address Deficiencies from FDA for Gimoti™ NDA

April 2, 2019

SOLANA BEACH, Calif., April 02, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its 505(b)(2) New Drug Application (NDA) for Gimoti ™ for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The CRL, which cites fewer issues than the recent multidisciplinary review letter, states that FDA has determined it cannot approve the NDA in its present form and provides recommendations to address the two remaining approvability issues in an NDA resubmission. The issues are related to clinical pharmacology and product quality/device quality. The Agency did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal pharmacokinetic (PK) study. The Agency stated the overall lower mean C_{max} was driven by the data from these few subjects. Without the aberrant doses, the Company's analysis shows the data met the bioequivalence criteria for both men and women. The Agency recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from previously planned registration batches of commercial product to be manufactured by the Company. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution after actuation of the sprayer device.

"We believe that the issues cited in the CRL, which were related to concerns over reproducible dose delivery, can be addressed. We look forward to meeting with FDA to gain a full understanding of the Agency's requirements for approval and remain committed to bringing our novel nasal formulation of metoclopramide to patients," said Dave Gonyer, President and CEO.

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 addressability of the approvability issues cited by FDA in the CRL; Evoke's plans to meet and work with FDA on the CRL deficiencies; and the potential for an NDA resubmission. 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 and successfully address the deficiencies raised in the CRL, including as a result of adverse findings from a root cause analysis or data from newly manufactured product batches; FDA may not agree with Evoke's conclusion of the root cause analysis or may require Evoke to conduct additional studies; the inherent risks of clinical development of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the PK data; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; Evoke will require substantial additional funding to address the deficiencies raised in the CRL, 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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