Evoke Pharma Requests Type A FDA Meeting to Plan for Resubmission of Gimoti™ NDA

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SOLANA BEACH, Calif., June 27, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has submitted a type A meeting request and meeting package to the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) dated April 1, 2019 regarding Evoke's New Drug Application (NDA) for Gimoti™ for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.

The purpose of the meeting is to discuss and gain clarity on the approvability issues relating to clinical pharmacology and product quality/device quality described in the CRL. During the meeting, Evoke plans to discuss the Company's strategy to address these issues as well as any other matters pertaining to the steps required for the resubmission of the Gimoti NDA. No safety concerns were raised and no additional clinical data were requested in the CRL.

"We have been working diligently to prepare the meeting package required at the time a type A meeting request is submitted to FDA. We look forward to meeting with the Agency to discuss our plans to address the issues raised in the CRL," commented Dave Gonyer, President and CEO. "As recommended by FDA, we have initiated the following: a root cause analysis of the variability observed in the pharmacokinetic bridging study, and manufacture of registration batches of Gimoti. We expect both these initiatives will support resubmission of our NDA."

The type A meeting, if granted, is expected to occur within thirty days of FDA's receipt of the meeting request and meeting package. Evoke will provide an update on the timing of resubmission of the NDA for Gimoti after receipt of the FDA's final meeting minutes, which typically become available within thirty days after the type A meeting.

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 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, an investigational nasal spray formulation of metoclopramide, for the relief of symptoms associated 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 addressability of the approvability issues cited by FDA in the CRL; the potential for a Type A meeting to occur and Evoke's plans at such meeting and generally with respect to addressing 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 to schedule a Type A meeting; 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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