# Evoke Pharma Receives Notice of Allowance from USPTO for Gimoti™

January 27, 2020

SOLANA BEACH, Calif., Jan. 27, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for the Gimoti™ trademark.

Gimoti is Evoke's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis. The U.S. Food and Drug Administration (FDA) is currently reviewing the New Drug Application (NDA) for Gimoti and has set a target goal date under the Prescription Drug User Fee Act (PDUFA) of June 19, 2020.

"We continue to build the Gimoti brand in preparation for potential product launch later this year. We remain excited for the possibility to provide a new product to those suffering from gastroparesis, especially those who experience delayed digestion of oral medications," commented Dave Gonyer, President and CEO. "Additionally, with our recent commercial partnership with EVERSANA, we have laid the foundation to bring Gimoti to market in order to help patients more efficiently and rapidly."

**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 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 product launch for Gimoti; the timing and results of any decision regarding the Gimoti NDA from the FDA, including whether FDA will act by the PDUFA target goal date; Evoke's belief that Gimoti, if approved, can will provide an alternative to patients suffering from gastroparesis; and whether Evoke's partnership with EVERSANA Life Sciences has laid the foundation for efficient and rapid commercialization of Gimoti, if approved. 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 scope of trademark protection may not provide the protections Evoke expects; the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; Evoke may be unable to timely and successfully address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti, 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; 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.

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