



## **Evoke Announces FDA Submission of New Drug Application for Gimoti™**

June 4, 2018

**Company to host a corporate update conference call today, June 4, 2018 at 4:30pm EST**

SOLANA BEACH, Calif., June 04, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the submission of 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.

"Our NDA submission for Gimoti represents a significant step forward for Evoke and Gimoti, which has the potential to meaningfully improve the lives of patients who suffer from the devastating symptoms of gastroparesis," commented Dave Gonyer, President and CEO. "Women represent an estimated 80% of all patients with the disease, which is characterized by debilitating episodes of nausea, vomiting, abdominal pain and bloating associated with delayed emptying of the stomach's contents after meals. Vomiting and gastric emptying delays cause unpredictable absorption of food and oral medications which complicates glucose control and can lead to dehydration and malnutrition. Existing oral treatment options may be ineffective during an acute flare, which we believe creates the need for a nonoral treatment option. Gimoti delivers metoclopramide, a well-characterized motility and antiemetic drug, as a nasal spray. We believe that Gimoti can make an important difference in the lives of these patients and we look forward to FDA approval."

Based on FDA timelines for review of the initial NDA submission, and Evoke's NDA submission on Friday, June 1, 2018, the Company expects to receive notification from FDA the filing was accepted for substantive review in early August 2018.

### **Conference Call and Webcast**

Evoke will hold a conference call on Monday, June 4, 2018 at 4:30pm EST to discuss this NDA submission and provide a corporate update. Participants should dial 1-877-407-0789 (United States) or 1-201-689-8562 (International) and mention Evoke Pharma. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at [www.evokepharma.com](http://www.evokepharma.com).

After the live webcast, the event will be archived on Evoke's website for one year. In addition, a telephonic replay of the call will be available until June 11, 2018. The replay can be accessed by dialing 1-844-512-2921 (United States) or 1-412-317-6671 (International) with confirmation code 13680477.

### **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](http://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 acceptance and approval, if any, of the NDA for Gimoti; the need for a nonoral treatment option for women suffering from gastroparesis; and the size of the patient population. 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 disagree that the existing safety database and efficacy data is sufficient to allow an NDA submission and approval, including risks associated with Cmax falling below the bioequivalence range in the comparative exposure PK trial and the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration; the FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; the inherent risks of clinical development of Gimoti; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will accept its NDA for Gimoti for substantive review or that Evoke will obtain regulatory approval for or successfully commercialize Gimoti; Evoke will require substantial additional funding to conduct any new safety trials required by the FDA, and may be unable to raise capital when needed, including to fund ongoing operations; 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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Source: Evoke Pharma, Inc.