

Evoke Pharma Announces Issuance of a New U.S. Patent Covering Methods of Use for Gimoti®

June 2, 2021

New patent expands intellectual property protection for nasal delivery of metoclopramide and is expected to be FDA Orange Book listed

SOLANA BEACH, Calif., June 02, 2021 (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 US patent No. 11,020,361 to the Company related to Gimoti[®] (metoclopramide) nasal spray. The patent covers methods of use for nasal delivery of metoclopramide for the treatment of gastroparesis.

Gimoti is Evoke's nasal spray product for the relief of symptoms in acute and recurrent diabetic gastroparesis. The U.S. Food and Drug Administration (FDA) approved the New Drug Application for Gimoti in June 2020. This new patent, entitled "Nasal Formulations of Metoclopramide," carries a patent term to at least 2029 and is expected to be listed in the FDA's Orange Book.

"We are pleased to announce the issuance of this new U.S. patent which further validates that Gimoti is innovative and novel. We believe Gimoti provides a new and effective option for treating patients that have erratic absorption of oral medications, as it is the first and only outpatient non-oral treatment to help improve the quality of life for patients suffering with diabetic gastroparesis," commented Dave Gonyer, President and CEO. "The issuance of this patent strengthens the intellectual property protection for Gimoti and supports our commercial efforts to make Gimoti the treatment of choice in the gastroparesis market."

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 developed, commercialized and markets Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adults.

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 GI symptoms as well as other systemic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Prior to FDA approval to commercially market Gimoti, metoclopramide was only available in oral and injectable formulations and remains 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: whether the new patent will be listed in the FDA Orange Book; Evoke's expectations on the scope of any patent protections; and Evoke's belief that Gimoti provides an effective option for treating patients that have erratic absorption of oral medications. 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 risk that the patent will not be added to the FDA Orange Book and the timing thereof; Evoke's ability to obtain and maintain intellectual property protection for GIMOTI; 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.