



Evoke Pharma Announces FDA Orange Book Listing of U.S. Patent for Gimoti®

June 8, 2021

SOLANA BEACH, Calif., June 08, 2021 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that its US patent No. 11,020,361 for Gimoti® (metoclopramide) nasal spray is now listed in the U.S. Food and Drug Administration (FDA) publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the "Orange Book". 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. FDA approved the New Drug Application for Gimoti in June 2020. As previously announced on June 2, 2021, the United States Patent and Trademark Office (USPTO) issued US patent No. 11,020,361 entitled "Nasal Formulations of Metoclopramide" for Gimoti. This new patent is now listed in the FDA's Orange Book and carries a patent term to at least 2029.

"We are pleased to expand and strengthen our intellectual property protection for Gimoti through the listing of our latest patent in the FDA's Orange Book," commented David Gonyer, President and Chief Executive Officer of Evoke Pharma. "We firmly believe Gimoti, as the first and only outpatient non-oral treatment option for gastroparesis, offers an innovative option for treating patients that have erratic absorption of oral medications. We are excited to protect our technology for Gimoti's method of use and look forward to continuing our mission to improve the quality of life for patients suffering from diabetic gastroparesis."

Patents listed in the Orange Book cover drugs that the FDA has approved and deemed both safe and effective for the general public's use. Inclusion in the book's list of patents can make it easier for drug makers to monitor for new generic drugs that could potentially arrive on the U.S. market and infringe on their patents.

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.

Follow Gimoti on Facebook: <https://www.facebook.com/Gimoti-metoclopramide-nasal-spray-104672345100289>.

Follow Evoke Pharma on Facebook: <https://www.facebook.com/Evoke-Pharma-Inc-131313647029724>

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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: Evoke's expectations on the scope of any patent protection for Gimoti. 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's ability to obtain, maintain and successfully enforce intellectual property protection for Gimoti; Evoke's and EVERSAN's ability to successfully drive market demand for Gimoti; Evoke's ability to obtain additional financing as needed to support its operations; the COVID-19 pandemic may continue to disrupt Evoke's and EVERSAN's business operations impairing the ability to commercialize Gimoti and Evoke's ability to generate any product revenue; Evoke's dependence on third parties for the manufacture of Gimoti; Evoke is entirely dependent on the success of Gimoti; inadequate efficacy or unexpected adverse side effects relating to Gimoti that could result in recalls or product liability claims; and other risks and uncertainties 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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