



Evoke Pharma Announces FDA Orange Book Listing of New GIMOTI Patent

November 27, 2023

GIMOTI now holds four listed patents with coverage through 2029

SOLANA BEACH, Calif., Nov. 27, 2023 (GLOBE NEWSWIRE) -- [Evoke Pharma, Inc. \(NASDAQ: EVOK\)](#), a specialty pharmaceutical company focused primarily on treatments for gastrointestinal (GI) diseases with an emphasis on GIMOTI® (metoclopramide) nasal spray, announced that its recently issued U.S. patent related to GIMOTI, No. 11,813,231 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 titled "Nasal Formulations of Metoclopramide" covers a collection of nasal solutions of metoclopramide and its characteristics when formulated. This new patent is now listed in the FDA's Orange Book and carries a patent term to 2029. The listing of the patent in the Orange Book adds additional patent protection for GIMOTI beyond the prior three listed patents.

"Due to our relentless efforts to continuously realize the significant commercial potential of GIMOTI and the need for an improved treatment solution for diabetic gastroparesis, our IP portfolio now boasts an impressive set of patents and four FDA Orange Book listings," commented Matt D'Onofrio, President and Chief Operating Officer of Evoke Pharma. "We are proud to have achieved this milestone as we aim to redefine the standard for gastroparesis treatment by providing GIMOTI, a direct route to deliver medication leading to less hospitalizations than oral metoclopramide."

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.

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About Gimoti™ (metoclopramide) nasal spray

GIMOTI is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Important Safety Information

WARNING: TARDIVE DYSKINESIA

- Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.
- Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.
- Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use.

GIMOTI is not recommended for use in:

- Pediatric patients due to the risk of developing tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates.
- Moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (creatinine clearance less than 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

GIMOTI is contraindicated:

- In patients with a history of tardive dyskinesia (TD) or a dystonic reaction to metoclopramide.
- When stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).
- In patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor.
- In patients with epilepsy. Metoclopramide may increase the frequency and severity of seizures.
- In patients with hypersensitivity to metoclopramide. Reactions have included laryngeal and glossal angioedema and bronchospasm.

Potential adverse reactions associated with metoclopramide include Tardive dyskinesia (TD), other extrapyramidal effects (EPS), parkinsonism symptoms, motor restlessness, neuroleptic malignant syndrome (NMS), depression, suicidal ideation and suicide, hypertension, fluid retention, hyperprolactinemia, effects on the ability to drive and operate machinery. Most common adverse reactions ($\geq 5\%$) for GIMOTI are: dysgeusia, headache, and fatigue. These are not all of the possible side effects of GIMOTI. Call your doctor for medical advice about whether you should take GIMOTI and the possible risk factors and side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 term of 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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Source: Evoke Pharma, Inc.