Evoke Pharma Receives Notices of Allowance for Two Additional US Patent Applications Protecting GIMOTI®

December 3, 2024

SOLANA BEACH, Calif., Dec. 03, 2024 (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, today announced that it has received notices of allowance for two U.S. patent applications by the United States Patent and Trademark Office, further expanding the company's robust intellectual property estate for its innovative GIMOTI ® (metoclopramide) nasal spray.

The two patent applications, U.S. 17/366,839 and U.S. 17/366,818, entitled "Nasal Formulations of Metoclopramide," provide Evoke with additional claims protecting the intranasal administration of metoclopramide for the treatment of gastroparesis. When issued, these patents will bolster the Company's position as the provider of the only FDA-approved, non-oral, patient administered therapy for acute and recurrent diabetic gastroparesis in the US. The two patents are expected to be Orange Book listable and expire at the end of 2029.

One of the key challenges in treating gastroparesis is ensuring effective drug absorption, as delayed stomach emptying often compromises the efficacy of orally administered medications. GIMOTI bypasses the GI tract, offering patients a reliable and effective treatment option.

"These new patents further solidify GIMOTI's position as a groundbreaking therapy in the gastroparesis treatment landscape," said Matt D'Onofrio, CEO of Evoke Pharma. "GIMOTI remains the only FDA-approved metoclopramide nasal spray, offering a novel solution for patients with diabetic gastroparesis who face significant challenges with oral medications. Data from patient support groups show that many patients are unable to find relief with oral therapies. Our most recent real-world head to data show that patients can get relief with Gimoti. With no competing intranasal products in development and a history of regulatory hurdles for other therapies in this space, these patents reinforce GIMOTI's uniqueness and strengthen our ability to build an important market product. We are proud to continue setting the standard for innovation in gastroparesis treatment."

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 our FDA approval to commercially market GIMOTI, metoclopramide was only available in oral and injectable formulations. Metoclopramide remains the only drug currently approved in the United States to treat gastroparesis.

Visit www.EvokePharma.com for more information.

Follow GIMOTI on Facebook
Follow Evoke Pharma on LinkedIn
Follow Evoke Pharma on X

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, and effects on the ability to drive and operate machinery. Most common adverse reactions (≥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: guidance regarding 2024 net product sales; potential future prescribing trends for GIMOTI based on Evoke’s or EVERSANA’s marketing efforts; Evoke’s commercialization plans, including the potential that GIMOTI could become the standard of care for gastroparesis; the potential for additional funds from the exercise of outstanding warrants and Evoke’s expected cash runway. 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 may not be able to achieve its guidance for 2024 including as a result of decreased demand for GIMOTI; Evoke’s and EVERSANA’s ability to successfully drive market demand for GIMOTI; Evoke’s ability to obtain additional financing as needed to support its operations; Evoke may use its capital resources sooner than expected; warrant holders may choose not to exercise any of the outstanding warrants; 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; Evoke’s ability to maintain intellectual property protection for GIMOTI; 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.

Investor & Media Contact:

Daniel Kontoh-Boateng

DKB Partners

Tel: 862-213-1398

dboateng@dkbpartners.net

Source: Evoke Pharma, Inc.