Evoke Pharma Highlights GIMOTI as a Leading Solution for Gastroparesis Treatment as Domperidone Supply Ends

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FDA posts update as mechanism to obtain unapproved Domperidone expected to lose supply in early 2025

Gimoti remains only approved drug shown to reduce hospitalizations, emergency room and medical office visits and related costs compared to oral metoclopramide

SOLANA BEACH, Calif., Dec. 19, 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, underscores its commitment to patients and healthcare providers managing gastroparesis in light of FDA's recent update regarding domperidone supply. As the sole FDA-approved nasal spray treatment for acute and recurrent diabetic gastroparesis in adults, GIMOTI® (metoclopramide) is uniquely positioned to address the ongoing needs of patients facing challenges with alternative therapies.

The FDA recently posted: *"Efforts made in the interim to identify an alternative source [of domperidone] have been unsuccessful. The current supply will be exhausted as early as the first or second quarter of 2025, at which time this program will no longer be able to supply domperidone for treatment use under your expanded access IND. FDA understands that this may pose challenges as you continue to care for your patient(s). We are making you aware of this development now so that you may begin to explore other treatment strategies." (https://www.fda.gov/drugs/investigational-new-drug-ind-application/how-request-domperidone-expanded-access-use)*

Domperidone, while used internationally for gastroparesis treatment and other GI conditions, has never been approved for use in the United States due to safety concerns, particularly its association with cardiac arrhythmias and sudden cardiac death. Despite this, some patients accessed domperidone under FDA's expanded access program when other treatments proved insufficient. FDA's recent announcement regarding the discontinuation of domperidone supply further highlights the urgent need for safe, effective, and accessible therapies like GIMOTI for patients struggling with gastroparesis.

Gastroparesis is a debilitating GI disorder wherein delayed stomach emptying, causes significant nausea, vomiting, early satiety, and abdominal pain often leading to dehydration, malnutrition and frequent ER visits and hospitalizations. These patients, particularly those who struggle eating a solid meal, often have issues taking oral medications either because they cannot easily take medicine (difficulty swallowing) may not keep medicines down (nausea and vomiting) or will not absorb medicine (due to delayed gastric emptying). Having effective treatments and routes of administration that can deliver medicine reliably are increasingly important.

Patient Advocate, Melissa VanHouten, stressed, "This news will have a negative impact on the gastroparesis community, so it is critically important to communicate this change to patients and their providers. People with gastroparesis had very few options prior to this news and the fact that there is only one FDA approved compound remaining for my community is unacceptable. That said, it is important for patients and providers to re-educate themselves about the options that are available, like oral metoclopramide and GIMOTI, and for all stakeholders to reduce the barriers to access to these and other medications that will improve their quality of life."

Matt D'Onofrio, CEO of Evoke Pharma, commented, "FDA's recent announcements highlight the critical need for reliable treatment options for patients. We believe GIMOTI addresses many needs of patients with gastroparesis and diabetes through its unique nasal spray delivery. It remains the only non-oral therapy that bypasses the GI tract, addressing the core defect of delayed emptying, and provides a practical and proven solution to relieve symptoms"

Strong Real-World Evidence Supports GIMOTI's Commercial Promise
Evoke Pharma remains committed to driving innovation and delivering value to patients, providers, and payors with strong supportive evidence. Real-world data has demonstrated significant clinical benefits of GIMOTI, including a **60% reduction in emergency room visits** and a **68% decrease in hospitalizations** compared to oral metoclopramide. Importantly, 61% of the patients on GIMOTI were previously on oral metoclopramide, suggesting that patients who previously did not receive an optimal benefit on oral might significantly benefit by switching to GIMOTI. Additionally, GIMOTI has shown a substantial reduction in overall healthcare costs, underscoring its potential to improve outcomes while reducing the burden on the healthcare system.

Mr. D'Onofrio added, "We are proud to support patients and providers with GIMOTI, a treatment that combines innovation with proven efficacy. As alternative treatment options like domperidone become unavailable or harder to access, GIMOTI's unique value proposition becomes even clearer, providing reliable symptom relief and improving quality of life for gastroparesis patients without a major burden on healthcare resources, patients, or payors."

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.

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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 (≥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, the potential market opportunity for GIMOTI, Evoke’s partnership with ASPN Pharmacies, growth in prescriptions, patients taking GIMOTI and the conversion of prescriptions to fills, 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.

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