Evoke Pharma, Inc. Supports Gastroparesis Awareness Month

August 8, 2024

Collaborating with advocacy groups to amplify gastroparesis awareness for millions of patients worldwide

Call for action to improve health and access for patients

SOLANA BEACH, Calif., Aug. 08, 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, together with EVERSANA™, a leading provider of global commercial services to the life science industry, joins the gastroparesis community in recognizing Gastroparesis Awareness Month throughout August and supporting the millions of people living with gastroparesis or suffering from associated symptoms of the condition. Established by the International Foundation for Gastrointestinal Disorders (IFFGD) and recognized each year in August by IFFGD and other organizations, Gastroparesis Awareness Month is intended acknowledge the challenges of living with gastroparesis – symptom burdens, identifying right therapeutic options, and lifestyle modifications while helping to educate patients and their loved ones on managing the condition.

Matt D'Onofrio, CEO of Evoke Pharma commented, "In nearly two decades of working with the GI community and developing GIMOTI from a concept to a reality for gastroparesis patients, I have seen firsthand the dreadful impact gastroparesis has on patients and their families. I applaud the work of organizations like IFFGD, Gastroparesis Patient Association for Cures and Treatment, Inc (G-PACT), Association of Gastrointestinal Motility Disorders (AGMD), and The Oley Foundation (OLEY) for their efforts in improving the understanding and awareness of this condition. At Evoke, we are dedicated to ensuring no patient suffering from diabetic gastroparesis goes untreated despite their economic background. This is made possible through our assistance programs when private insurance does not cover GIMOTI."

A 2022 research study indicated that approximately 2% of the U.S. population is affected by gastroparesis.[1] Gastroparesis, commonly known as stomach paralysis, is a disorder where food moves slower than normal or a delay in emptying of the contents from stomach into the intestines, without any observable blockage. This condition affects people of all ages but is four times more prevalent in women. Symptoms include chronic nausea, vomiting, bloating, inability to eat a full meal, abdominal pain, weight loss, and discomfort. Gastroparesis can be debilitating, requiring hospitalization and significantly impacting the quality of life.

"Our organization is in constant communication with healthcare providers and patient advocates to understand the trajectory of the disease and patients' treatment experiences. According to a 2019 survey conducted by IFFGD, many patients (67%) rated their current state of health as fair or poor and most respondents (60%) were not satisfied with available treatments for gastroparesis. This needs to change. These interactions have also highlighted the ongoing popularity of GLP-1 weight loss medications potentially linked to gastroparesis in patients. This media attention has heightened awareness of gastroparesis with the general public and with many specialties within the medical community, however more awareness, and frankly more action is needed to improve the health and daily life of patients." Mr. D'Onofrio added. "With the healthcare resource utilization data we've generated alongside EVERSANA, we believe GIMOTI is optimally positioned to become the standard of care for diabetic gastroparesis treatment, a goal we are tirelessly working to attain."

After over a decade of development, Evoke Pharma launched GIMOTI in June 2020 as the only outpatient gastroparesis treatment approved by the FDA in over 30 years. It remains the only non-oral form of metoclopramide available for adult patients suffering from acute and recurrent diabetic gastroparesis. To date, over 4,000 patients have received GIMOTI. Supported by EVERSANA's market research, GIMOTI has significantly impacted patients and the healthcare system in terms of treatment efficacy, healthcare resource burden, and cost. Surveys show that patients prescribed GIMOTI have significantly fewer doctor's office visits, emergency room visits, or inpatient hospitalizations in the six months following therapy compared to patients taking oral metoclopramide. This reduction in healthcare facility use has saved diabetic gastroparesis patients and insurers over $15,000 in expenses over a six-month period with GIMOTI versus oral metoclopramide.

More can be done to support patients and providers in managing this debilitating disease. Evoke Pharma calls on:

- People with gastroparesis continue seeking support and resources to advocate for your care. The way you feel today should not be the best you ever feel.
- Providers, caregivers and families take extra moments to genuinely seek to understand how people with gastroparesis are doing. Many are not "doing fine" and need our empathy and support. We need to hear them and include them in their care plan.
- Payers to open access to medicines to support patients in reducing their symptoms and reduce restrictions to care. Beneficiaries with gastroparesis have comorbidities and they use significant healthcare resources. Medicines may help.

To learn more about Gastroparesis disease advocacy and support communities and resources they provide, please visit the following

websites:

International Foundation for Gastrointestinal Disorders (IFFGD) - https://iffgd.org/

Gastroparesis Patient Association for Cures and Treatments, Inc. (G-PACT) - https://www.g-pact.org/

Association of Gastrointestinal Motility Disorders (AGMD) - https://agmdhope.org/

Gastroparesis Pie Face Challenge - https://www.facebook.com/gastroparesispiefacechallenge/

The Oley Foundation - https://oley.org/

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, 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.

References

1. Huang IH, Schol J, Khatun R, Carbone F, Van den Houte K, Colomier E, Balsiger LM, Törnblom H, Vanuytsel T, Sundelin E, Simrén M, Palsson OS, Bangdiwala SI, Sperber AD, Tack J. Worldwide prevalence and burden of gastroparesis-like symptoms as defined by the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis. United European Gastroenterol J. 2022 Oct;10(8):888-897. doi: 10.1002/ueg2.12289. Epub 2022 Aug 19. PMID: 35985672; PMCID: PMC9557951.

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