Evoke Pharma Announces Acceptance of an Abstract at the Academy of Managed Care Pharmacy (AMCP) Annual Meeting 2023

January 18, 2023

Real-world study compares diabetic gastroparesis patient utilization of healthcare resources before and after initiation of GIMOTI

SOLANA BEACH, Calif., Jan. 18, 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, today announced that its abstract entitled **"Real-World Healthcare Resource Utilization of Patients Treated with Metoclopramide Nasal for Diabetic Gastroparesis (DGP)"** will be presented at the Academy of Managed Care Pharmacy (AMCP) annual meeting taking place in San Antonio, TX from March 21-24, 2023.

GIMOTI is the first and only FDA-approved novel nasal formulation of metoclopramide that is commercially available and specifically designed to deliver a non-oral dose of metoclopramide for the relief of symptoms in adults with acute and recurrent DGP. Prior to GIMOTI's approval by the U.S. Food and Drug Administration (FDA), oral metoclopramide was the only FDA-approved outpatient treatment for patients suffering from DGP.

The poster presentation at the AMCP annual meeting will cover the data from a retrospective cohort analysis of 294 patients receiving nasal metoclopramide (GIMOTI). The study was designed to evaluate whether GIMOTI reduced the need for doctor's office, emergency department, inpatient, and outpatient visits across all settings for patients using GIMOTI versus the period prior to GIMOTI initiation.

Lead author, Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health, emphasized the challenges faced by patients with gastroparesis who have limited treatment options and often experience flare-ups. "Gastroparesis flares lead to numerous emergency care visits and hospitalizations due to dehydration, malnutrition, or glucose control problems, and as a result, the cost of care for these patients is substantial. The nasal delivery option provides a novel method of treating gastroparesis that allows healthcare providers to directly dose medication to patients whose timing of absorption for oral medications can be unpredictable." Dr. Kunkel continued, "It is critical for both clinicians and insurers to understand the potential effectiveness of this approach in not only improving the symptoms of patients with gastroparesis, but also reducing the overall utilization of healthcare resources. We appreciate the opportunity to present and share these data with our colleagues attending the AMCP meeting in March."

"The positive response to the clinical utilization of GIMOTI gathered from patients through our studies and surveys is highly encouraging and continues to emphasize the major treatment gap GIMOTI fills every day for people suffering from diabetic gastroparesis. Patients and health care providers need new treatment options and are eager to learn whether these options can improve their symptoms and reduce their need to visit the ER or take more invasive steps to improve their condition. The presentation at the AMCP meeting will show how GIMOTI utilization is supporting the continuum of care for patients," commented Chris Quesenberry, Chief Commercial Officer for GIMOTI.

Details of the poster presentation are as follows:

Poster Title: Real-World Healthcare Resource Utilization of Patients Treated with Metoclopramide Nasal for Diabetic Gastroparesis (DGP)

Presentation Date/Time: Thursday, March 23 from 11:30 a.m. – 2:30 p.m. CST

Location: Henry B. Gonzalez Convention Center, San Antonio, TX

Poster No: K2

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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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 http://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 potential of GIMOTI to improve the quality of life for patients suffering from diabetic gastroparesis; potential future prescribing trends for GIMOTI; and the need for new treatments for diabetic gastroparesis. 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 EVERSANA’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 EVERSANA’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.