



Evoked Pharma & EVERSANA Announce Compelling Real-World Data on the Impact of GIMOTI in Reducing the Utilization of Healthcare Resources to be Presented at the Academy of Managed Care Pharmacy (AMCP) 2023

March 23, 2023

Data Demonstrated Reduced Use of Healthcare Resources among Patients Treated with GIMOTI

SOLANA BEACH, Calif., March 23, 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, and EVERSANA Life Science Service LLC, an independent provider of global commercial services to the life science industry, today announced a summary of real-world data on the positive impact of GIMOTI usage in decreasing the utilization of healthcare resources by patients with diabetic gastroparesis (DGP). The full data set, authored by Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health, will be presented in a poster session at today's Academy of Managed Care Pharmacy (AMCP) Annual Meeting in San Antonio, Texas.

The data describes results of a study that highlights *healthcare resource utilization data* (HCRU) in diabetic gastroparesis patients before and after taking GIMOTI. HCRU is the description and quantification of patients' total usage of healthcare services such as hospitalization or how often they visit their physician in office. DGP is a chronic disorder of the stomach characterized by delayed gastric emptying and a range of symptoms, including nausea, vomiting, early satiety, bloating, and abdominal pain, which drastically reduce a patient's quality of life.

Studies have found that patients with diabetic gastroparesis were admitted to the hospital an average of four times per year and that approximately 30% of patients with diabetes admitted for gastroparesis had to be readmitted within 30 days. The cost to the healthcare system is significant and the impact on the patients and their families is considerable. A retrospective U.S. claims study demonstrated that, on average, patients recently diagnosed with diabetic gastroparesis experience higher emergency room costs and greater inpatient and outpatient care costs than diabetic patients without gastroparesis.

For decades, oral metoclopramide has been the most common and only approved treatment for patients suffering from diabetic gastroparesis. In June 2020, GIMOTI became the first FDA-approved nasal spray for patients suffering from acute and recurrent diabetic gastroparesis, an innovative transition from oral metoclopramide. With over two years of GIMOTI being commercially available, the study's goals were to examine HCRU (physician office, hospital outpatient, inpatient hospitalization, and emergency room visits) among patients treated with GIMOTI. The data presented at AMCP 2023 highlights a retrospective cohort study of 294 patients comparing the use of these healthcare resources in the six months prior to vs. the six months after using GIMOTI.

Select data points and key findings from the real-world evidence study are outlined below:

- Of the 294 patients, 60.5% received oral metoclopramide prior to initiation of GIMOTI and 43.8% were treated with oral metoclopramide in the immediate six months prior to the initiation of GIMOTI
- 77% of patients studied were female with an average age of 52.1 years
- Patients received an average of 2.6 prescriptions for GIMOTI during the six-month follow up period
- For All-Cause HCRU data (image 1), the **mean number of physician office visits was significantly less** in the post-period at 2.0 compared to the pre-period at 2.2 ($p=0.03$)
- For Nausea, Vomiting and DGP-associated HCRU data (image 2), the **mean number of physician office and hospital outpatient visits was significantly less** in the post-period for dropping 0.29 to 0.18 ($p<0.01$) and 1.6 to 1.0 ($p<0.01$) respectively.

[Image 1: All-Cause HCRU in the Pre-nasal MCP period vs. Post-nasal MCP period](#)

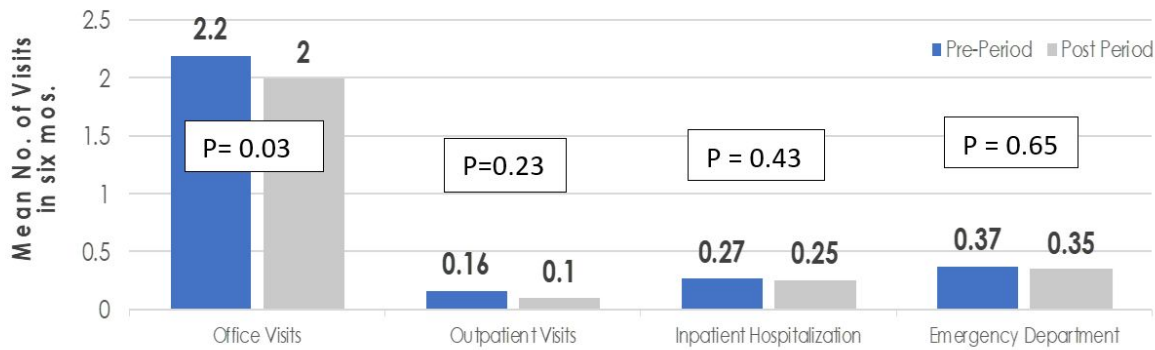
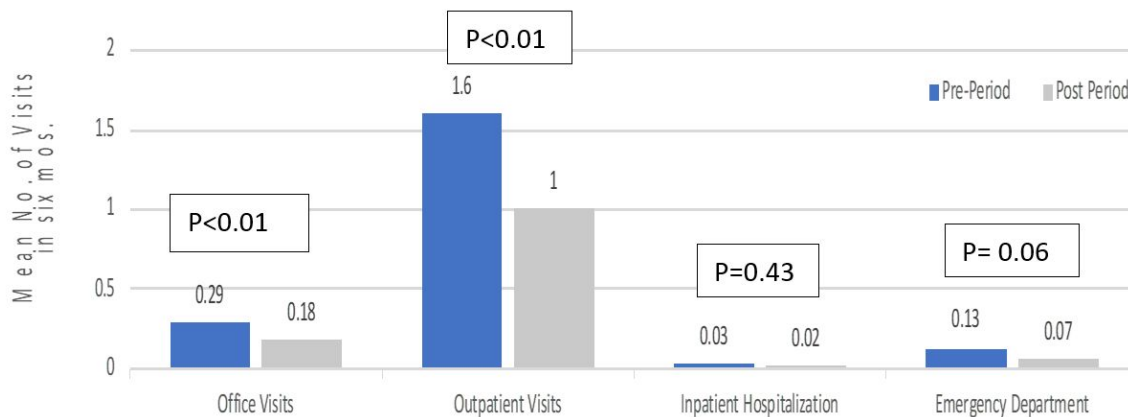


Image 2: Nausea, Vomiting, and DGP-associated HCRU in the Pre-nasal MCP period vs. Post-nasal MCP Period



Conclusions:

- For DGP-related HCRU both Office Visits and Hospital Outpatient Visits significantly declined in the post-period vs. pre-period, respectively.
- The mean number of All-Cause Office Visits was significantly less in the post-period vs. the pre-period.
- There were fewer inpatient hospitalizations and Emergency Department visits for both All-Cause and DGP related although statistical significance was not achieved.

Full poster presented at AMCP 2023 available on Evoke Pharma website: <https://investor.evokepharma.com/static-files/f415aaa8-ba1d-45b7-ab8e-4523196797e8>

Lead author Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health, commented, "Oral metoclopramide has been the standard of care for DGP patients, but the introduction of nasal metoclopramide into the treatment landscape and the evidence we have gathered makes it apparent that there is room for improvement. The reduction in healthcare resource utilization showcases the numerous benefits of this innovative approach."

"This data reinforces our commitment to advancing the field of gastroparesis treatment and improving the DGP patient experience. We believe every patient deserves access to innovative non-oral treatment options, and we are happy and encouraged daily to be in a position where we can advance this mission by ensuring the availability of GIMOTI in the marketplace for patients and healthcare providers," stated Matt D'Onofrio, President and COO of Evoke Pharma.

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 EVERSANA

EVERSANA™ is a leading independent provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 650 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences solutions for a healthier world. To learn more about EVERSANA, [visit eversana.com](http://visit.eversana.com) or connect through [LinkedIn](#) and [Twitter](#).

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: GIMOTI's potential to reduce HCRU by diabetic gastroparesis patients; Evoke's plans to ensure the availability of GIMOTI in the marketplace for patients and healthcare providers; and Evoke's belief that GIMOTI can improve treatment of 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 and EVERSANA's ability to successfully drive market demand for GIMOTI; Evoke's ability to obtain, maintain and successfully enforce intellectual property protection for GIMOTI; the results of market research studies may not predict acceptance by patients, healthcare providers or payors; inadequate efficacy or unexpected adverse side effects relating to GIMOTI that could result in recalls or product liability claims; Evoke's ability to obtain additional financing as needed to support its operations; Evoke is entirely dependent on the success of GIMOTI; Evoke's dependence on third parties for the manufacture of 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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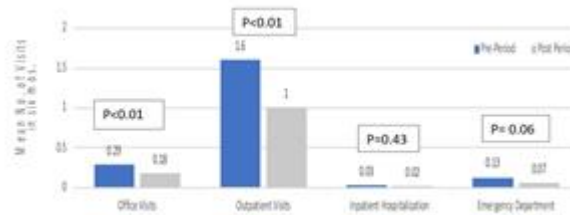
Source: Evoke Pharma, Inc.

Image 1



All-Cause HCRU in the Pre-nasal MCP period vs. Post-nasal MCP period

Image 2



Nausea, Vomiting, and DGP-associated HCRU in the Pre-nasal MCP period vs. Post-nasal MCP Period