Real-World Data Presented by Evoke Pharma and EVERSANA at Digestive Disease Week 2023 Shows Gimoti® Meaningfully Reduces Utilization of Healthcare Resources

May 9, 2023

Patients treated with Gimoti® (metoclopramide) nasal spray showed statistically significant fewer emergency department visits, inpatient hospitalizations, and physician office visits than patients who were treated with oral metoclopramide

SOLANA BEACH, Calif., May 09, 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™ a leading provider of global commercial services to the life science industry, announced the details of its presentation at Digestive Disease Week (DDW) 2023 demonstrating that GIMOTI reduces healthcare resource utilization for patients with diabetic gastroparesis versus patients on oral metoclopramide.

Selected by DDW leadership for presentation alongside a total of only six (6) meritorious clinical abstracts from more than 3,500 that were submitted, Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health, delivered the data to the AGA Distinguished Plenary Session. The study, guided by Dr. Kunkel and supported by EVERSANAs Real World Evidence team, confirmed a hypothesis that improved symptom control in diabetic gastroparesis (DGP) patients treated with nasal metoclopramide would result in lower *healthcare resource utilization* (HCRU) compared to patients on oral metoclopramide. 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.

Diabetic gastroparesis is an intermittent 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 and can impair absorption of oral medications. According to a 2020 report, DGP patients experience three times greater emergency department (ED) costs, three times greater inpatient admission costs, and two times greater outpatient costs compared to non-gastroparesis patients.

Given this debilitating condition places significant burden on patients and insurance payers, the researchers who conducted the study sought to compare the frequency of physician office, outpatient facility, ED, and inpatient hospital visits for patients with DGP treated with nasal metoclopramide (NMCP) versus oral metoclopramide (OMCP). Select data points and key findings from the real-world data analysis are outlined below:

- Cohorts were selected from patients prescribed NMCP and from within a national database of 100 million patients of those receiving OMCP; these groups were statistically matched using a propensity score with **257** subjects in each category for a total of **514** patients.
- **77%** of patients were female.
- **31.1%** of subjects in both groups experienced an ED visit or inpatient hospitalization during the 6-months prior to index.
- Patients treated with NCMP had **99** fewer physician office visits, **1** additional outpatient visit, **34** fewer inpatient hospitalizations and **84** fewer ED visits **for DGP-related causes** in the 6 month follow up period (image 1).
- Patients treated with NMCP had **124** fewer physician office visits, **55** fewer outpatient facility visits, **37** fewer inpatient hospitalizations, and **167** fewer ED visits **for any cause** in the 6-month follow-up period (image 2).
- Statistically, the likelihood of a patient treated having a DGP related physician office visit was **36% lower** in the NMCP cohort (image 3). Similarly, for inpatient hospitalizations and emergency department visits the likelihood was **68% and 60%** lower, respectively, for NMCP-treated patients versus OMCP.

Image 1:

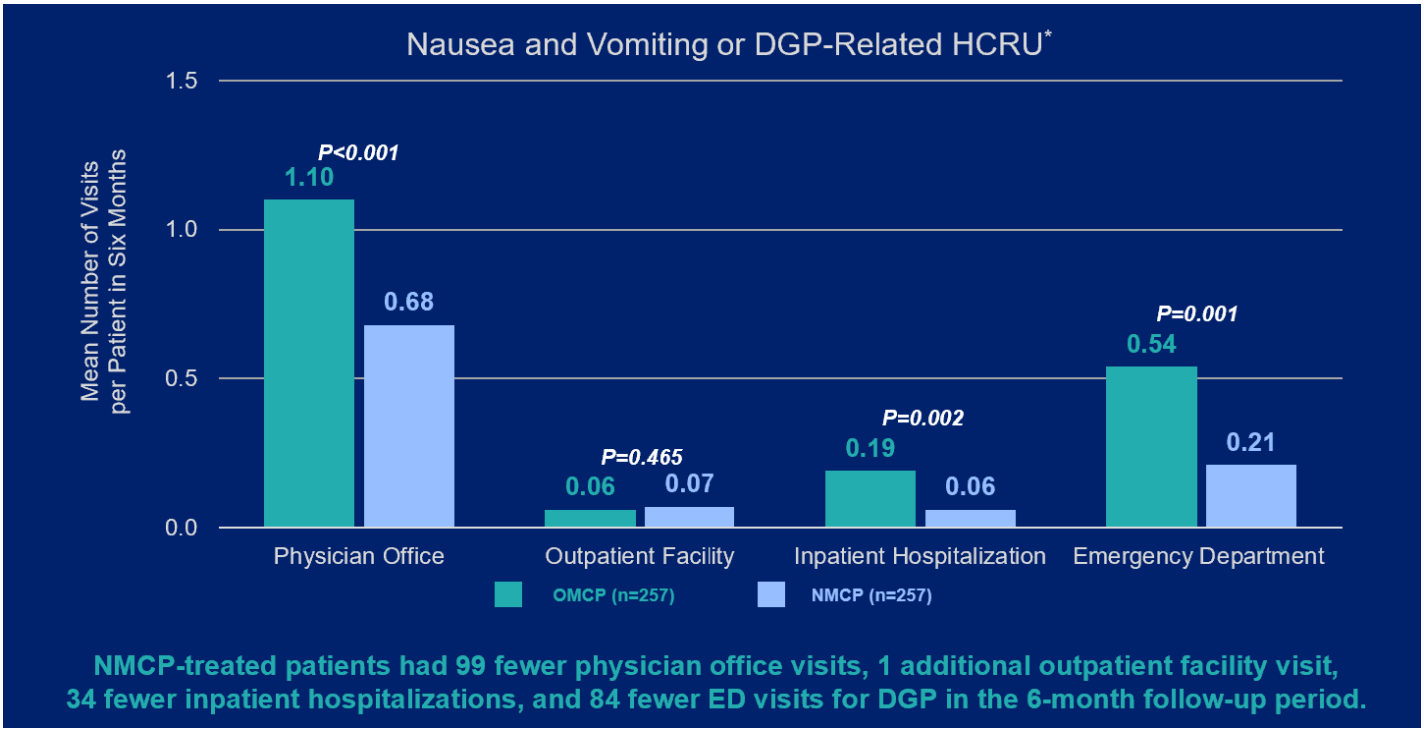


Image 2:

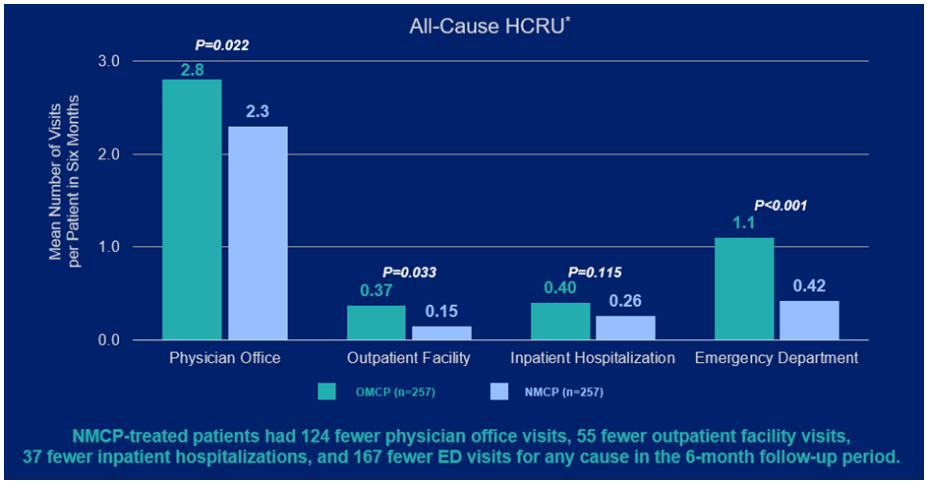


Image 3:

	IRR (95% CI)	*P*-value	IRR (95% CI)	*P*-value
Physician Office	0.64 (0.47, 0.87)	0.005	0.83 (0.67, 1.02)	0.077
Outpatient Facility	0.22 (0.03, 1.16)	0.098	0.41 (0.17, 1.02)	0.053
Inpatient Hospitalization	0.32 (0.14, 0.7)	0.005	0.64 (0.36, 1.13)	0.128
Emergency Department	0.40 (0.2, 0.78)	0.007	0.39 (0.25, 0.61)	<0.001

The likelihood of a patient treated having a DGP-related physician office visit was 36% lower in the NMPC cohort. Similarly, for inpatient hospitalizations and ED visits the likelihood was 68% and 60% lower, respectively, for NMCP-treated patients versus OMCP.

Conclusions:

- In a matched comparison, NMCP-treated patients had significantly fewer nausea and vomiting or DGP-related office visits, ED visits, and inpatient hospitalizations in the 6 months following start of therapy.
- The reduction in DGP-related HCRU equated to an avoidance of 99 physician office visits, 84 fewer ED visits, and 34 fewer inpatient hospitalizations for NMCP patients versus OMCP patients in a 6-month period.
- Overall, the likelihood of a DGP patient treated with NMCP visiting the ED or being admitted to the hospital was less than half that of patients treated with OMCP during the same period.

Full data presentation at DDW 2023 available on Evoke Pharma website: https://investor.evokepharma.com/static-files/d45f574f-699a-48bd-86f1-85d6883eedb0

Lead author Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health commented, “This unique data set asserts that the route of metoclopramide administration is imperative for successful DGP treatment. The positive effects of nasal metoclopramide versus oral metoclopramide on patients and healthcare resources is worth noting and encouraging for the GI motility community. Considering the need for a more effective DGP therapy, it is important to utilize a treatment that can be absorbed by the patient, so it can work, such as GIMOTI.”

“The consistency of data on the GIMOTI experience amongst patients and providers including this DDW presentation is deeply important to inform the healthcare community and mirrors anecdotal descriptions of successful treatments we’ve received from physicians recently. We strongly believe GIMOTI has the potential to be the standard of care for DGP treatment,” commented 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.
Follow GIMOTI on Facebook
Follow Evoke Pharma on Facebook
Follow Evoke Pharma on LinkedIn
Follow Evoke Pharma on Twitter

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 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 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: GIMOTI’s potential to reduce HCRU by diabetic gastroparesis patents; 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.

Investor Contact:
Daniel Kontoh-Boateng
DKB Partners
Tel: 862-213-1398
dboateng@dkbpartners.net

EVERSANA Contact:
Sarah Zwicky
Tel: 414-434-4691
sarah.zwicky@eversana.com

Infographics accompanying this announcement are available at:

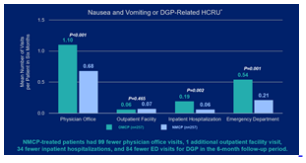
https://www.globenewswire.com/NewsRoom/AttachmentNg/b50d0557-de3d-45ab-aa23-a3b6c5514cba

https://www.globenewswire.com/NewsRoom/AttachmentNg/adc9db7b-c5b6-4eca-8a13-0ddcaf78d1c5

https://www.globenewswire.com/NewsRoom/AttachmentNg/cdafc0c6-02ad-40a8-ba70-a65fa372f7b1

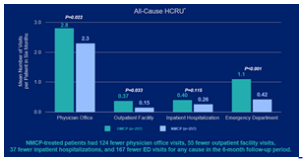
Source: Evoke Pharma, Inc.

Image 1:



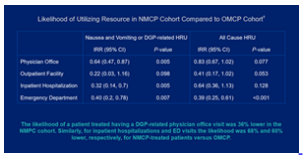
Nausea and Vomiting or DGP-Related HCRU*

Image 2:



All-Cause HCRU*

Image 3:



Likelihood of Utilizing Resource in NMCP Cohort Compared to OMCP Cohort†