

# Evoke Pharma's Real-World Healthcare Utilization Data Comparing GIMOTI® to Oral Metoclopramide to Be Presented at Digestive Disease Week (DDW) 2023

May 4, 2023

Compelling data elevated to distinguished DDW oral plenary session

GIMOTI to be showcased in additional activities at conference

SOLANA BEACH, Calif., May 04, 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<sup>®</sup> (metoclopramide) nasal spray, announced that the abstract entitled "Reducing Real-World Healthcare Resource Utilization For Patients With Diabetic Gastroparesis (DGP) Treated with Metoclopramide Nasal Spray Versus Oral Metoclopramide" will be presented at Digestive Disease Week (DDW) 2023 taking place from May 6-9, 2023 at the McCormick Place, Chicago.

David C. Kunkel, MD, Gastroenterologist and Associate Professor of Medicine at University of California San Diego Health, will deliver an oral presentation of the abstract in the AGA Clinical Practice Section Distinguished Abstract Plenary Session at DDW on Tuesday, May 9<sup>th</sup> at 8:20 AM CDT. The oral presentation will focus on the impact of GIMOTI to reduce healthcare resources across several settings, such as physician's offices visits, emergency room visits, and inpatient and outpatient hospital stays from a retrospective analysis of 514 diabetic gastroparesis patients compared those receiving oral metoclopramide.

Plenary sessions at DDW are the forum for highlighting the year's best research abstracts that have the potential to impact clinical practice and make a significant contribution to the field of gastroenterology, as determined by the conference organizers. These real-world data were selected for presentation alongside a total of only six (6) meritorious clinical abstracts from more than 3,500 that were submitted.

GIMOTI is the first and only FDA-approved nasal formulation of metoclopramide 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. By bypassing the stomach and being directly absorbed in the bloodstream, GIMOTI may provide relief to patients experiencing acute and recurrent flares, especially nausea, vomiting and abdominal pain, which can result in increased visits to their doctors and reliance on costly emergent care (emergency department visits and hospitalizations).

An additional poster presentation entitled "Use of Machine Learning to Identify Gastroparesis Patient Suitable for Nasal Spray Metoclopramide" will be presented by Pierantonio Russo, MD, Chief Medical Officer of EVERSANA. This study used large claims databases and clinical features of GIMOTI-prescribed patients to predictively model patients in the US who might be appropriate for GIMOTI based on having similar clinical features.

In addition, Evoke Pharma will showcase their GIMOTI nasal spray and supporting educational materials at **DDW booth #3334.** Evoke encourages all attendees to visit their booth for additional discussion to learn more about the product and its impact on patients.

# Details of the presentations are as follows:

1. **AGA Distinguished Plenary Presentation Title:** "Reducing Real-World Healthcare Resource Utilization for Patients with Diabetic Gastroparesis (DGP)

Treated with Metoclopramide Nasal Spray Versus Oral Metoclopramide"

Presentation Date & Time: May 9, 2023, from 8:00 AM to 9:30 AM CDT

Presenter: Dr. David C. Kunkel, Gastroenterologist and Associate Professor of Medicine at UC San Diego Health

Location: McCormick Place, Chicago, IL

2. Poster Presentation Title: "Use of Machine Learning to Identify Gastroparesis Patient Appropriate for Nasal Spray Metoclopramide" ( Poster Number:

Su1651)

Session Date and Time: May 7, 2023 from 12:30 PM to 1:30 PM CDT

Presenter: Pierantonio Russo, MD, Corporate Chief Medical Officer, EVERSANA

Location: McCormick Place, Chicago, IL

## 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.

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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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> 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 impact of the healthcare utilization resource study for Gimoti. 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 forwardlooking 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.