Real-World Data Analysis Reveals a Lower Risk of Tardive Dyskinesia (TD) with Metoclopramide than Previously Reported

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Presented as a Poster of Distinction at Digestive Disease Week (DDW) 2022, showed a 98.8 per 100,000 (0.1%) incidence of TD among gastroparesis patients treated with metoclopramide

Supports Safety Profile of Only Approved Molecule in US to Treat Symptoms of Acute and Recurrent Diabetic Gastroparesis

SOLANA BEACH, Calif., May 23, 2022 (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 the presentation of a real-world data analyses demonstrating a lower risk of tardive dyskinesia (TD) associated with metoclopramide usage compared to previous reports at the world's premier gastroenterology conference, Digestive Disease Week ® (DDW) 2022, which is taking place from May 21-24 in San Diego, CA. The poster entitled *Revisiting the Risk of Tardive Dyskinesia with Metoclopramide Use: A Real-World Data Driven Epidemiology Study from 2011-2020* was awarded a "Poster of Distinction" by the American Gastroenterological Association (AGA) for poster presentations at DDW.

Evoker's flagship product, GIMOTI, is an 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 diabetic gastroparesis. Non-oral delivery is an important treatment option as gastroparesis causes oral medications to be unpredictably absorbed and vulnerable to one of the key symptoms of the disease, vomiting.

"Metoclopramide has been the primary prescription for diabetic gastroparesis treatment for more than four decades, resulting in numerous clinical research publications which include adverse events associated with the drug," stated Dr. Richard McCallum, Professor and Founding Chair of the Department of Medicine at Texas Tech University Health Science Center, El Paso and first author. "Together with the co-authors of this study, we are highly gratified to have been provided the opportunity to better define, understand and obtain perspective on the safety profile of metoclopramide, the only FDA approved therapy for the treatment of gastroparesis and also to update the medical literature on the incidence of TD. By analyzing a database of 80 million patients, this "real world" experience with this agent provides important information on those who might be most at risk for developing TD and help healthcare providers target therapy for those patients that are appropriate candidates for metoclopramide products, like GIMOTI."

Previous publications have suggested a strong causal relationship between metoclopramide and TD and reported varying frequencies of TD with metoclopramide use (from 1% to 15%). These reviews are largely outdated, have small sample sizes and different outcome definitions.

This analysis is the largest examination ever conducted to understand the risk of TD. The retrospective analysis was conducted with administrative claims data representing approximately 35% of the US population using the Truven Health MarketScan Commercial Database. The data gathered between January 1, 2011 and December 31, 2020, comprised an excess of 300 unique employers, 25 different health plans, and 240 million covered lives studying patients with at least twelve (12) months of enrollment in a health insurance plan. Risk ratios were utilized to gauge the association between TD and renal dysfunction, diagnosis of mental health disorders, dopamine receptor blocking agents (DRBA) use, and diabetes. Results of the study concluded that TD is rare among metoclopramide-treated patients, with an incidence of 33.4 per 100,000, and among metoclopramide-treated gastroparesis patients, it was 98.8 per 100,000. In addition, age and sex appear to be significant risk factors for TD, with the highest TD incidence reported among elderly females. Additional risk factors for TD include renal dysfunction, coadministration of DRBAs, diagnosis of mental health disorders, and diabetes. The incidence of TD was also found to increase with prolonged metoclopramide use, with the greatest risk of TD observed after 24 to 48 months of chronic metoclopramide use.

DDW is the largest international gathering of physicians, researchers, and academics in the fields of gastroenterology, hepatology, endoscopy, and GI surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the AGA, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine, and technology.

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: the potential benefits of GIMOTI for patients with 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: the data from a retrospective analysis may not be as robust as data from a controlled clinical trial and such data does not otherwise effective the black box warning on the Gimoti label related to TD; 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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