Evoke Pharma and EVERSANA Announce Acceptance of Abstract for Poster of Distinction Presentation at Digestive Disease Week (DDW) May 2022

February 24, 2022

Revisiting the risk of tardive dyskinesia with metoclopramide use in diabetic gastroparesis: results of a real-world data driven epidemiology study

SOLANA BEACH, Calif., and CHICAGO, Feb. 24, 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 (GIMOTI), today announced that the results of a retrospective analysis of United States (US) administrative claims data that examined the association between tardive dyskinesia (TD) and potential risk factors will be presented at the annual Digestive Disease Week Meeting in San Diego, CA taking place from May 21-24, 2022.

Evoke's flagship product, GIMOTI, is an FDA-approved novel 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 diabetic gastroparesis.

Selected as a poster of distinction during DDW 2022, the presentation titled: "Revisiting the Risk of Tardive Dyskinesia with Metoclopramide Use: A Real-World Data Driven Epidemiology Study From 2011-2021" will cover the data analytics of an 80 million patient database (Truven Health MarketScan®) used to conduct the most comprehensive analysis to date on the risk of metoclopramide-induced tardive dyskinesia. In the limited literature available, the reported incidence of TD varies widely.

"With the emergence of scaled real-world data (RWD), we can now interrogate how on market drugs perform in large patient populations. Leveraging the Truven Marketscan database we were able to examine the association between TD and risk factors such as age, sex, underlying medical diagnosis and exposure to drugs, including metoclopramide," stated Brigham B. Hyde, Ph.D., President, Data & Analytics at EVERSANA. "The previous literature on the subject were comprised of smaller, decades-old studies that may not represent today's standard of care. As a result, TD incidence in metoclopramide, patients may have been overestimated, and risk factors, comorbidities, and comedications in those cases were poorly understood."

"It is a very special opportunity to update the group of professionals attending DDW on the relationship between metoclopramide, gastroparesis and tardive dyskinesia utilizing the world's largest database," stated Dr. Richard McCallum, Professor and Founding Chair of the Department of Medicine at Texas Tech University Health Science Center and first author. "We believe this information will prove invaluable to healthcare providers in the treatment of their patients with diabetic gastroparesis."

Details of the poster presentation are as follows:

Session Title: Gastroparesis and Small Intestinal Dysmotility

Presentation Title: "Revisiting the Risk of Tardive Dyskinesia with Metoclopramide Use: A Real-World Data Driven Epidemiology Study From 2011-2021"

Date: May 21, 2022

Time: 12:30 p.m. – 1:30 p.m. PDT

Location: San Diego Convention Center

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 EVERSANA
EVERSANA™ is a leading provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science 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 www.fda.gov/medwatch or call 1-800-FDA-1088.

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Source: Evoke Pharma, Inc.