Evoke Pharma Announces Approval of GIMOTI® to the Texas Medicaid Preferred Drug List

April 19, 2022

Market access improves with approximately 5 million people in the Texas Medicaid patient network

SOLANA BEACH, Calif., April 19, 2022 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused primarily on treatments for gastrointestinal (GI) diseases, announced today that GIMOTI® (metoclopramide) nasal spray a novel treatment solution for the treatment of symptoms associated with diabetic gastroparesis (DGP), has been added to the Texas Medicaid Preferred Drug List (PDL), effective April 12, 2022. This decision supports reimbursement for GIMOTI on the Texas Medicaid formulary and associated programs which provides healthcare to an estimated 5 million people.

According to Texas Health and Human Services, preferred drugs are medications recommended by the Texas Drug Utilization Review Board for their efficaciousness, clinical significance, cost effectiveness, and safety. The Medicaid Formulary contains all products, including those on the preferred drug list, available to people enrolled in Medicaid. GIMOTI will be available for those that fail treatment with any preferred drug class. “We are pleased with Texas’ decision to add GIMOTI to their PDL and making it available for patients in need of symptomatic relief for acute and recurrent symptoms of DGP. We believe most patients diagnosed and treated for DGP have previously taken at least one of the agents currently on Texas Medicaid formulary, so this status is in line with current practice and our expectations,” stated Matt D’Onofrio, MBA, Evoke Pharma Chief Business Officer. Preferred products are available without prior authorization, although they may be subject to other requirements. Drugs identified as non-preferred on the PDL require a prior authorization.

“Increasing access for GIMOTI has been a fundamental goal since we introduced the product in the wake of the COVID-19 pandemic in 2020-2021. We will continue to work to progress the growing list of Medicaid coverage jurisdictions. Similar to the recent announcement concerning our approval on the New York State Medicaid program, this approval from Texas Health and Human Services underscores their belief in the need for a non-oral treatment option for patients with diabetic gastroparesis. We are committed to ensuring that GIMOTI is available to all patients requiring a novel treatment solution for diabetic gastroparesis. We look forward to exploring further possibilities to broader accessibility for patients and healthcare providers,” commented David Gonyer, R.Ph., Evoke Pharma President and CEO.

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

Follow Evoke Pharma on LinkedIn: https://www.linkedin.com/company/evoke-pharma/

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 potential future prescribing trends for GIMOTI based on Evoke’s or EVERSANA’s marketing efforts; Evoke’s commercialization plans, including its plans to increase awareness of and access to GIMOTI; and Evoke’s future capital requirements. 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 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 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; Evoke’s ability to maintain intellectual property protection for 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 & Media Contact:
Daniel Kontoh-Boateng
DKB Partners
Tel: 862-213-1398
dboateng@dkbpartners.net

Source: Evoke Pharma, Inc.