



FDA Approves Evoke's GIMOTI™

June 19, 2020

*Commercial Partner EVERSANA Prepares for GIMOTI Launch
Evoke Extends Cash Runway into 2021*

SOLANA BEACH, Calif., June 19, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for GIMOTI™ (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

"We are extremely pleased to have received FDA approval to commercially market GIMOTI in the United States. This approval represents the first novel pharmaceutical treatment for gastroparesis in several decades. Many times, patients do not experience adequate relief of their gastroparesis symptoms from current treatments, representing a significant need for a new approach to therapy. We are excited to be able to offer health care providers and their patients a unique non-oral treatment option to relieve symptoms and help improve their quality of life," said David Gonyer, R.Ph., President and CEO.

"Patients with gastroparesis suffer from characteristic symptoms such as nausea, abdominal pain, bloating, early satiety as well as vomiting which can be severe and debilitating. These patients often have erratic absorption of orally administered drugs due to delayed gastric emptying," stated Henry Parkman, MD, Stanley H. Lorber Research Endowment Fund and Chair, and Director, Gastroenterology Motility Laboratory, School of Medicine at Temple University. "Unlike oral medications, GIMOTI is administered nasally, bypassing the diseased GI track, allowing the drug to enter the bloodstream directly and therefore may provide predictable delivery of the therapy."

"Together with our partner EVERSANA, we are now fully focused on executing our commercialization strategy for GIMOTI by leveraging EVERSANA's integrated suite of capabilities and highly experienced sales and marketing team," continued David Gonyer, R.Ph. "We anticipate initiating commercial sales in the fourth quarter of 2020."

The FDA approval of GIMOTI allows Evoke to access its existing \$5 million line of credit from EVERSANA to support manufacturing and other aspects of GIMOTI's commercialization. As of May 31, 2020, the Company's cash and cash equivalents were approximately \$4.7 million. Evoke believes, based on its current operating plan, that its cash and cash equivalents, together with the EVERSANA line of credit, will support the company's operations into 2021, without consideration of potential GIMOTI revenue.

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.

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 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.

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 timing of the commercial launch of GIMOTI and commercial activities to be conducted by EVERSANA; the size of the gastroparesis market and the potential of GIMOTI to provide an important new alternative to current treatment options; and Evoke's projected cash runway and potential to access the EVERSANA line of credit. 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 launch and drive market demand for GIMOTI and the timing thereof; Evoke's ability to obtain additional financing as needed to support its operations, including through the EVERSANA line of credit which is subject to certain customary conditions; the COVID-19 pandemic may 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 delay or prevent commercialization, or that could result in recalls or product liability claims; our ability to obtain and maintain intellectual property protection for GIMOTI; and other risks 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:
The Ruth Group
Tram Bui
Tel: 646-536-7035
tbui@theruthgroup.com



Source: Evoke Pharma, Inc.