

Evoke Pharma and EVERSANA Extend Commercialization Partnership to Further Support GIMOTI

February 2, 2022

SOLANA BEACH, Calif. and CHICAGO, Feb. 02, 2022 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company primarily focused on treatments for gastrointestinal (GI) diseases, and EVERSANA Life Science Services, LLC, an independent provider of global commercial services to the life science industry, today announced the extension of their agreement to continue collaborating on the commercialization and distribution of Gimoti[®] (metoclopramide) nasal spray in the United States through the end of 2026.

According to the original agreement signed in January 2020, Evoke retains ownership of the Gimoti NDA and legal, regulatory, and manufacturing responsibilities for Gimoti. EVERSANA utilizes its internal sales organization and other commercial functions for market access, marketing, distribution, and other patient support services. Evoke records sales for Gimoti and retains more than 80% of the net product profits once the parties' costs are reimbursed. This amendment increases the percentage of net product profit retained by Evoke and accelerates the reimbursement of commercialization costs to Eversana after the product breaks even on a monthly basis. The initial term provided in the original agreement was five years following FDA approval, June 19, 2025, but this amendment will extend the term of the agreement through December 31, 2026.

"Our market research for Gimoti continues to reinforce significant unmet medical need for patients with diabetic gastroparesis and shows strong receptiveness to the potential benefits in favor of delivering treatment outside of the gastrointestinal tract," shared Jim Lang, CEO of EVERSANA, "Together we created a fully integrated commercialization model for this therapy and today we are expanding our investment in this partnership as we continue to believe in the product, the market and the patient need. Through the extension of our multi-year partnership, we are poised to further increase the access of Gimoti to patients and physicians as part of our broader commercial strategy."

"Gimoti remains the most novel product to treat patients that suffer from symptoms associated with diabetic gastroparesis. Although the pandemic has slowed new product launches across the industry, we continue to see market research that is highly supportive of the opportunity for Gimoti. More importantly, patients have described remarkable benefits after initiating Gimoti therapy. We continue to see expanding enrollments and filled prescriptions for the brand and believe in the long-term opportunity for Gimoti. We are excited to continue leveraging the expertise of EVERSANA's team for our sales and distribution efforts, given their large-scale commercialization capabilities for products generated by life science companies," commented Dave Gonyer, CEO of Evoke Pharma.

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 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.

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 market research; and Evoke's commercialization plans and the long term opportunity 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 and EVERSANA's ability to successfully drive market demand for GIMOTI; the results of our market research may not predict prescribing trends by doctors or acceptance by patients, and are not intended to reflect or imply actual prescriptions or sales to date; 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.

Investor Contact:

Daniel Kontoh-Boateng DKB Partners Tel: 862-213-1398 dboateng@dkbpartners.net



Source: Evoke Pharma, Inc.