



## **Evoke and EVERSANA Announce Commercial Launch of Gimoti™**

October 26, 2020

### **Product launch provides healthcare providers a novel treatment approach for patients suffering from symptoms of acute and recurrent diabetic gastroparesis**

SOLANA BEACH, Calif. and CHICAGO, Oct. 26, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, and EVERSANA™, a leading provider of global commercial services to the life science industry, are pleased to announce the commercial launch of Gimoti™ (metoclopramide) nasal spray for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

GIMOTI is specifically designed to address the unique needs of adult patients with diabetic gastroparesis by delivering an established treatment as a nasal spray that bypasses the GI tract. Adults suffering from diabetic gastroparesis may have unpredictable stomach emptying and may vomit their medications. For these reasons, oral administration may be problematic since drug absorption in the small intestine requires gastric emptying. GIMOTI, which was approved by the U.S. Food and Drug Administration in June 2020, is the first and only treatment for diabetic gastroparesis that enters the bloodstream through the nasal mucosa.

"Patients with diabetic gastroparesis often have erratic absorption of orally administered drugs due to delayed gastric emptying or are unable to keep from vomiting pills traditionally used to treat symptoms of this disease. Unlike oral medications, GIMOTI is administered nasally, bypassing the need for absorption in the GI system, allowing the drug to enter the bloodstream directly and avoiding the problem of unpredictable stomach emptying," stated Henry Parkman, M.D., Stanley H. Lorber Research Endowment Fund and Chair, and Director, Gastroenterology Motility Laboratory, School of Medicine at Temple University. "For these patients suffering from debilitating symptoms such as nausea, abdominal pain, bloating, early satiety, and vomiting, GIMOTI is an important alternative to the current standard of care to help those that suffer from this disease."

"The commercial launch of our novel treatment for the underserved market of patients suffering from diabetic gastroparesis is an important milestone reflecting years of clinical and product development," commented David Gonyer, R.Ph., President and CEO of Evoke. "GIMOTI fills a major treatment gap by providing the current standard of care treatment through a non-oral delivery. With the support of an integrated commercial team from EVERSANA, we are confident in our ability to address the large and growing market opportunity. We are excited to provide patients and their prescribing physicians with a new important treatment option."

Jim Lang, CEO of EVERSANA, added, "Evoke's innovative approach is a welcome advancement that has the ability to change the continuum of care for treatment of adults suffering from the symptoms of diabetic gastroparesis. Powered by a full commercialization engine, a trained sales team will be immediately deployed to offer this novel approach to their targeted physician base. Patients will then get the full benefit of our access, distribution and adherence services, optimized by real-time analytics and actions. We look forward to commencing commercial availability of GIMOTI and supporting seamless physician adoption and patient access."

#### **IMPORTANT SAFETY INFORMATION**

##### **What is Gimoti™ (metoclopramide) nasal spray?**

GIMOTI is a prescription medicine used 30 minutes before meals and at bedtime for 2 to 8 weeks to relieve symptoms of slow stomach emptying in adults with diabetes. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks.

GIMOTI is not recommended for use in children under age 18.

##### **Important facts about GIMOTI**

This is a summary of important information you need to know about GIMOTI. This information does not take the place of talking with your healthcare professional about your medical condition or your treatment.

##### **What is the most important information I should know about GIMOTI?**

**GIMOTI can cause serious side effects, including: TARDIVE DYSKINESIA: Abnormal muscle movements, mostly of the face or tongue muscles. You cannot control these movements, and they may not go away even after stopping GIMOTI. Your chances of getting tardive dyskinesia increase**

- **The longer you take metoclopramide and the more metoclopramide you take. You should not take GIMOTI for more than 8 weeks at a time, and you should not take products containing metoclopramide (including GIMOTI) for more than 12 weeks at a time.**
- **If you are older, especially if you are an older woman (e.g., age 65 years and older)**
- **If you have diabetes**

Call your healthcare professional right away if you get movements you cannot stop or control, such as lip smacking, chewing, or puckering up your mouth; frowning or scowling; sticking out your tongue; blinking and moving your eyes; shaking of your arms and legs. **Do not use GIMOTI if you**

- Have a history of tardive dyskinesia or have a problem controlling your muscles and movements after taking GIMOTI or a medicine that works like GIMOTI
- Have stomach or intestinal problems that could get worse with GIMOTI, such as bleeding, blockage, or a tear in the stomach or bowel wall
- Have a type of tumor that can cause high blood pressure, such as pheochromocytoma
- Have epilepsy (seizures)
- Are allergic to metoclopramide. Stop taking GIMOTI right away and get emergency help if you have any of these symptoms:
  - swelling of your tongue, throat, lips, eyes, or face
  - trouble swallowing or breathing
  - skin rash, hives, sores in your mouth, or skin blisters

**Before starting GIMOTI**, tell your healthcare professional about all your medical conditions, especially if you have problems controlling your muscle movements after taking any medicine, Parkinson's disease, pheochromocytoma, kidney or liver disease, depression or mental illness, high blood pressure. Also tell your healthcare professional if you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, or drink alcohol.

Tell your healthcare professional about all the medicines you take, including prescription drugs and over-the-counter medicines, vitamins, and herbal supplements.

Speak with your healthcare professional before you start or stop any other medicines.

**Especially tell your healthcare professional if you take** another medicine that contains metoclopramide, such as Reglan® tablets, medicine for Parkinson's disease, blood pressure medicine, medicine for depression, especially a monoamine oxidase inhibitor (maoi), antipsychotic medicine used to treat mental illness, such as schizophrenia, insulin, medicines that can make you sleepy, such as anxiety medicines, sleep medicines, and narcotics

#### **What should I avoid while taking GIMOTI?**

**Do not drink alcohol while taking GIMOTI. GIMOTI may cause sleepiness or dizziness. Do not drive, operate machinery, or do potentially dangerous activities until you know how GIMOTI affects you.**

#### **What are other possible side effects of GIMOTI?**

**Other changes in muscle control and movement, Neuroleptic Malignant Syndrome, depression, thoughts about suicide, and suicide, high blood pressure, too much body water, and increased prolactin.**

**The most common side effects of GIMOTI include unpleasant taste after dosing, headache, and tiredness. These are not all the possible side effects of GIMOTI. Ask your healthcare professional for medical advice about side effects.**

You may report side effects related to Evoke Pharma products by calling 1-833-4-GIMOTI (1-833-444-6684) or emailing [GIMOTImedinfo@evokepharma.com](mailto:GIMOTImedinfo@evokepharma.com). If you prefer to report these to the FDA, either visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

**Please see complete [Prescribing Information](#), including **Boxed Warning**, **Medication Guide**, and **Instructions for Use**.**

#### **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](http://www.EvokePharma.com) for more information.

#### **About EVERSANA Life Science Services, LLC**

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](http://eversana.com) or connect through LinkedIn and Twitter.

#### **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 size of the gastroparesis market and the potential of GIMOTI to provide an important new alternative to current treatment options. 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, 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 result in recalls or product liability claims; Evoke's 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.

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