GIMOTI Receives Nomination for 2022 Healio Industry Breakthrough Award

September 14, 2022

GIMOTI recognized as a major disruptor in the gastroenterology field, including several large global pharmaceutical companies

Vote for GIMOTI as 2022 Healio Industry Breakthrough Product via Survey

SOLANA BEACH, Calif., Sept. 14, 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, today announced that its flagship product, GIMOTI has been nominated for Healio's Annual Disruptive Innovators Awards under the *Healio Industry Breakthrough Award* category. GIMOTI was selected amongst other novel gastroenterology products from major pharmaceutical companies.

Healio is an online source for in-depth specialty clinical information featuring the industry's best news reporting, dynamic multimedia, podcasts, opinion columns, CME, peer-reviewed journal, and a wide range of popular medical book titles across a wide array of medical specialties including gastroenterology. The Disruptive Innovators Awards hosted by Healio is an annual event to celebrate the trailblazers, movers, and industry name-makers that are creating a revolution in gastroenterology. Each nominee for the 2022 awards event has played a role in changing the face of gastroenterology and hepatology and shifted the status quo towards the betterment of the field.

GIMOTI is the first and only FDA-approved novel nasal formulation of metoclopramide that is 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. Non-oral delivery is an important treatment option as gastroparesis causes oral medications to be unpredictably absorbed and vulnerable to one of the key symptoms of the disease, vomiting.

"We are extremely honored to receive the nomination for GIMOTI as a Healio Disruptive Innovator. This recognition aligns with our patient-centric approach and core focus to ensure patients suffering from acute and recurrent diabetic gastroparesis have access to a more convenient and effective treatment option," commented David A. Gonyer, President, and CEO of Evoke Pharma.

Mr. Gonyer continued, "We believe this nomination further highlights the novelty of a non-oral treatment for a disease where traditional oral treatments are noted to be unreliable. This aligns with the FDA's comments within its assessment of patient experience data for GIMOTI that patients with gastroparesis may, in general, benefit from alternatives to oral solid dosage forms, including but not limited to metoclopramide[1]. We look forward to the Healio organization's unveiling of the award winners in each category and encourage all Evoke supporters to access the Healio survey and vote for GIMOTI."

Healio Disruptive Award Survey, please vote: https://www.surveymonkey.com/r/HC6HZ8W.

1. *Gimoti NDA Multidisciplinary Review FDA 6/18/2020 2. Gastroparesis: Clinical Evaluation of Drugs for Treatment FDA Guidance for Industry. Aug. 2019.*

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.
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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.