



Evoke Pharma Reaffirms Its Commitment to Patients with Gastroparesis Amid Industry Developments

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Gimoti remains the sole proprietary FDA approved treatment for symptoms of diabetic gastroparesis

SOLANA BEACH, Calif., Sept. 19, 2024 (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, reaffirms its commitment to improving the lives of patients suffering from diabetic gastroparesis in light of the recent decision by the U.S. Food and Drug Administration (FDA) to not approve Vanda Pharmaceuticals new drug application (NDA) for Tradipitant, an oral drug candidate for the treatment of symptoms in gastroparesis. Patients suffering from all forms of gastroparesis need additional agents to help treat this difficult disease, and we believe patients will be disappointed given the FDA's decision. Evoke continues to serve as a trusted partner for healthcare professionals and patients alike with its proven product, Gimoti[®] (metoclopramide), the first and only FDA-approved nasal spray treatment for acute and recurrent diabetic gastroparesis in adults.

"While challenges in the regulatory landscape affect all of us in the industry, Evoke remains focused on improving patient outcomes and expanding access to GIMOTI, the only non-oral outpatient treatment for acute and recurrent symptoms of diabetic gastroparesis, which has already demonstrated significant benefits in real-world settings," said Matt D'Onofrio, CEO of Evoke Pharma. "We have been able to provide Gimoti to over 4,000 patients since launch and continue to seek to inform patients and physicians about the benefits of non-oral treatments for this disease."

Diabetic gastroparesis is a serious condition and remains complex to effectively treat with only one FDA approved active molecule (metoclopramide) available. Gimoti, the nasal formulation of metoclopramide, was developed by Evoke Pharma specifically as an oral treatment due to the complexities of gastroparesis. Oral treatments are prone to faulty absorption due to the delayed gastric emptying blocking delivery or symptoms causing vomiting of pills, further complicating oral drug therapy.

Those suffering from diabetic gastroparesis, who often take several oral medications, know first-hand the problems ingesting and digesting pills or tablets with this disease. To confirm the impact of GIMOTI and the nasal route of administration, Evoke has provided the first ever comparative data in the gastroparesis field showing statistically significant improvement in patient outcomes between Gimoti and oral metoclopramide. This real-world data, presented at Digestive Disease Week 2023, showed that patients with diabetic gastroparesis using Gimoti experienced significant reductions in emergency room visits (-60%, $p=0.007$) and hospitalizations (-68%, $p=0.005$) compared to oral metoclopramide over a six-month period. Furthermore, 61.5% of patients in this study that were treated with Gimoti had previously taken oral metoclopramide, suggesting that some patients that did not experience relief of symptoms with oral metoclopramide gained relief with a new treatment of GIMOTI. A separate cost analysis revealed that GIMOTI reduced the total cost of care by approximately \$15,000 within the first six months of initiation compared to oral metoclopramide.

Evoke Pharma's commitment to quality and innovation continues to drive its mission to provide patients with reliable and effective treatments for gastroparesis. As the field evolves, particularly with the emergence of gastroparesis linked to GLP-1 receptor agonists, Evoke is positioning to respond to these new challenges with data to support clinical decision making.

"As we continue to explore the benefits of Gimoti in diabetic gastroparesis treatment, Evoke Pharma is striving to expand on our promise of providing innovative and accessible solutions for patients and healthcare providers," said Chris Quesenberry, Chief Commercial Officer of Evoke. "While having additional therapies would be beneficial to patients and providers, it would also be supportive of Evoke's goal to expanded diagnosis and treatment of patients, many of whom go years without a proper diagnosis or appropriate treatment. Gaining approval for a new treatment method has proven very difficult for gastroparesis. With this recent news, it brings the total to 14 treatments in last 15 years that have failed to gain regulatory clearance. We believe GIMOTI is an important new innovation for gastroparesis patients and we remain steadfastly committed to expanding our commercial reach to ensure more patients receive the clinical value and ability to return to normal daily activities," he added.

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.

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