

FDA grants marketing authorization for Vibrant a new drug-free treatment for adults with chronic constipation

Vibrant®'s unique drug-free treatment is thought to enhance colonic motility by augmenting the biological clock via mechanical stimulation of the colon

NEWTON, MASSACHUSETTS, UNITED STATES, August 30, 2022 /EINPresswire.com/ -- Vibrant Gastro Inc. announced today that the Food and Drug Administration (FDA) granted marketing authorization for the Vibrant®, an orally administered drug-free capsule, for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month.

Vibrant®'s unique drug-free treatment is thought to enhance colonic motility by augmenting the biological clock via mechanical stimulation of the colon. The FDA marketing authorization is based on the pivotal clinical trial results of 312 chronic idiopathic constipation patients, evaluating the efficacy and safety of Vibrant® treatment. The pivotal trial's outcomes demonstrated superiority with respect to both the proportion of patients with at least 1 additional complete spontaneous bowel movement per week compared to baseline, 40.51% in the treatment arm, compared to 22.92% in the control arm, a difference of 17.6% (chi-square p-value = 0.0011) and at least 2 additional complete bowel movements per week, 23.42% in the treatment arm, compared to 11.81% in the control arm, a difference of 10.0%. There were no SAEs reported in the Vibrant groups. Please refer to the Instructions for Use for the complete list of risks, warnings, and potential AEs(1).

Chronic constipation is a common gastrointestinal (GI) disorder with an estimated prevalence of 16% in the US(2). Costs to treat constipation are significant. It is estimated that 70–90% of patients with constipation in the US report bothersome symptoms such as bloating, straining, and hard stool persisting for many years, with a negative impact on health-related quality of life (HRQoL).

Vibrant® will be available for patients in early 2023 in select states, with gradual national expansion throughout the year.

“The development of Vibrant® highlights the kind of scientific advancement we need to address so many ailments today,” said gastroenterologist Satish Rao, M.D., Ph.D., a professor of medicine at the Medical College of Georgia, and a principal investigator (PI) in the phase III study. “The goal

of Vibrant® is to address a real problem in chronic constipation, which has made life very challenging for those who suffer from it. We believe the Vibrant System is a meaningful step towards achieving that goal.”

“Our vision is to accelerate the transition to drug-free treatments that enable millions of constipation patients to live more enjoyable lives by inventing solutions that synchronize and activate the body's natural gut-brain connection,” said Lior Ben Tsur, Vibrant Gastro CEO. “The FDA clearance of our first indication is an exciting milestone towards our vision and future indications expansion. Millions of chronic idiopathic constipation patients continue to use laxatives chronically with little to no relief of their recurring symptoms. Vibrant® provides the sufferers with an additional treatment option that is effective, safe and drug-free ”.

About Vibrant Gastro

Vibrant Gastro is the pioneer of the Synchronized Activation Method™, a first-in-class drug-free technology system augmenting the bio-rhythm in sync with the body`s natural biological clock.

The technology system allows future opportunities for developing data-driven personalized treatments and additional indications leveraging the gut-brain connection via the Enteric Nervous System (ENS) pathway.

Our mission is to create drug-free treatments that enable millions of constipation patients to live more enjoyable lives via new products that synchronize and activate the gut-brain connection to provide control over their bodies and predictable symptom relief.

Vibrant Gastro’s first indication is for treating adults with chronic idiopathic constipation (CIC) who have inadequate relief from laxatives after one month of use.

To learn more about Vibrant, visit www.vibrantgastro.com.

Contact for media inquiries:

Ben Feldman, Chief Marketing Officer

Ben.f@vibrantgastro.com

+972.58.6240336

Contact for investor relations:

Cathy Collis, Chief Commercial Officer

Cathy.c@vibrantgastro.com

+ 1 857.488.6620

References

1. Rao SSC et al. DDW 2022; Gastroenterology Volume 162, Issue 7, Supplement, S-124
2. The Humanistic and Economic Burden of Chronic Idiopathic Constipation in the USA: A

Systematic Literature Review. Clin Exp Gastroenterol. 2020; 13: 255–265.

+ +972 586240336

Ben Feldman, Chief Marketing Officer

Vibrant Gastro

ben.f@vibrantgastro.com

Visit us on social media:

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/588483585>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2022 Newsmatics Inc. All Right Reserved.