

GI Dynamics Announces Approval of the I-STEP Clinical Study in India

Trial to focus on reduction of hemoglobin A1c for patients diagnosed with type 2 diabetes and obesity

BOSTON & HYDERABAD, India--([BUSINESS WIRE](#))-- GI Dynamics Inc., a medical device company that is developing the EndoBarrier® System for patients diagnosed with type 2 diabetes and obesity, is pleased to announce that it has received regulatory approval to begin enrollment in the I-STEP clinical trial in India.

I-STEP is a multi-center, randomized, pivotal study evaluating the safety and efficacy of EndoBarrier® for glycemic improvement in patients with inadequately controlled type 2 diabetes and obesity and will be conducted exclusively in partnership with the Apollo Hospital System and Apollo Sugar Clinics. This study, which is intended to follow 100 subjects up to 24 months, will evaluate EndoBarrier® in patients who fall within a predetermined hemoglobin A1c range. All enrolled patients will follow a moderate intensity lifestyle and receive dietary counseling, along with standard practice medication management.

Diabetes has become a significant health problem in India, with [nearly 74 million](#) people suffering from the condition and a proportion of the population that has been undiagnosed. The number of people with diabetes in India is expected to grow to 125 million by 2045.¹

Obesity is a leading factor for type 2 diabetes, and worryingly, the prevalence of obesity in India is increasing faster than the world average.² According to an ICMR-INDIAB study, the prevalence rate of obesity and central obesity vary from 11.8% - 31.3% and 16.9% - 36.3% respectively.³

Apollo Sugar is a collaboration between Apollo Health & Lifestyle Limited and Sanofi Ltd.. Apollo Sugar is a division of Apollo Hospitals Group (Apollo), focused on the treatment of metabolic disorders, and operates an integrated network of centers of excellence for diabetes, obesity and endocrinology.

As the largest hospital system in India, Apollo has emerged as Asia's foremost integrated healthcare services provider, maintaining a robust presence of hospitals, pharmacies, primary care, secondary-care and diagnostic clinics across the healthcare ecosystem. Since its inception, Apollo has treated patients from 141 countries.

In addition to partnership in the I-STEP clinical trial, GI Dynamics and Apollo Sugar have agreed to work toward setting the terms of a joint-partnership that will focus on the marketing, distribution, and clinical support of EndoBarrier® to appropriate patients throughout India and Southeast Asia. Final terms of the proposed collaboration are subject to negotiation and will be disclosed upon completion.

Commenting on the collaboration, Anand P. Wasker, Chief Executive Officer of Apollo Sugar, said, "Apollo Sugar is pleased to partner with GI Dynamics to study EndoBarrier® as an innovative means of treating patients diagnosed with type 2 diabetes and obesity. We at Apollo Hospitals have always focused on providing advanced, safe, and effective treatments to our patients. We believe that EndoBarrier® can provide a novel and powerful clinical tool for our clinicians, and we look forward to studying EndoBarrier® in our hospitals, for patients based in India and Southeast Asia."

"As the incidence and risks of type 2 diabetes and obesity continue to increase throughout the globe, we see the I-STEP trial as an important step towards offering patients and clinicians another safe and effective treatment option. Through this partnership with Apollo Sugar, access to this therapy has the potential to significantly improve the disease management of millions of patients throughout India," stated Joe Virgilio, President and CEO of GI Dynamics.

About Apollo Sugar

Apollo Sugar is an innovative, single-specialty diabetes and endocrine healthcare service provider, formed as a collaboration between Apollo Health & Lifestyle and Sanofi Ltd. Recognizing the epidemic scale and complications of this disease in the region, the Apollo Hospitals Group created the Apollo Sugar model.

This initiative aims to reach out to the larger population and address the ever-increasing health concerns of type 1 and type 2 diabetes, gestational diabetes and prediabetes populations, with specialized and comprehensive multidisciplinary integrated care models that are personalized, intensive and proven to deliver results.

Apollo Sugar Clinics touches over 500,000 lives through treating their diabetes needs. This is made possible by the 100+ qualified Diabetologists and Endocrinologists who work from 75+ branches, across 21 cities.

For more information, please visit apollosugar.com

About GI Dynamics

GI Dynamics Inc. is the developer of the EndoBarrier® System, an endoscopically delivered device therapy which offers a non-surgical, alternative treatment for the treatment to type 2 diabetes and obesity. EndoBarrier® is not approved for sale in the United States and is limited by federal law to investigational use only.

Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information, please visit gidynamics.com.

References:

1. IDF Diabetes Atlas 2021, 10th Edition.
2. Luhar S et al. Forecasting the prevalence of overweight and obesity in India to 2040. PLoS ONE 2020;15(2).
3. Ahirwar R et al. 2018. Prevalence of obesity in India: A systematic review. Diabetes Metab Syndr 2018;13(1):318-321.

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