



Fractyl Health Demonstrates Significant Improvement in Glucose Control and Obesity in Preclinical Studies of its Rejuva GLP-1 Based Pancreatic Gene Therapy (GLP1 PGTx) Compared to Chronic Semaglutide at ADA's 83rd Scientific Sessions

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Revolutionary one-time pancreatic gene therapy resulted in up to 54% lower blood glucose and 20% lower total bodyweight than chronic semaglutide 10 nmol/kg/day in the db/db rodent model

Proprietary Fractyl delivery technology combined with proprietary AAV-based gene therapy results in preclinical proof-of-concept for the potential of a unique, localized, low-dose tissue-specific pancreatic gene therapy platform

Results raise potential for a one-time pancreatic gene therapy with GLP-1 based transgenes to overcome known challenges with existing GLP-1 based therapies in T2D and obesity

First-in-human diabetes and obesity studies targeted in 2024

LEXINGTON, Mass.—([BUSINESS WIRE](#))— Fractyl Health, an organ-editing metabolic therapeutics company focused on pioneering new approaches to the treatment of type 2 diabetes (T2D), presented preclinical findings from its Rejuva® program at the American Diabetes Association's 83rd Scientific Sessions. The oral presentation, "Targeted Pancreatic Gene Therapy: A Potent and Durable Treatment for Type 2 Diabetes and Obesity," highlighted the promising implications of the Rejuva platform in potentially reshaping the treatment landscape for type 2 diabetes (T2D) and obesity with a one-time, durable, tissue-specific gene therapy.

"We have been looking for a way to deliver the efficacy and durability of bariatric surgery without the surgery," said Geltrude Mingrone, Professor of Diabetes and Nutrition at King's College, London, and Associate Professor of Internal Medicine at Catholic University of Rome. "Here, a one-time administration of GLP1PGTx in rodent models suggests we have a pathway to get there. I look forward to seeing the results of human trials."

The groundbreaking results today unveiled a striking efficacy of single-dose GLP-1-based transgene compared to chronic semaglutide in the well-validated db/db rodent model for diabetes and obesity. The data presented corroborate the fundamental hypothesis that local delivery of GLP1 PGTx, driven by the insulin promoter, can potentially improve metabolic control in type 2 diabetes by protecting the pancreatic islet from failure.

Unlike current therapies, GLP1 PGTx has the potential to provide durable treatment benefit long after the treatment delivery itself is discontinued and may offer further benefits of GLP1 targeted principally to and within the pancreas. The therapy is enabled by Fractyl's development of both proprietary gene constructs and a proprietary delivery system, and leverages a decade of Fractyl research and device development.

"The fact that the pancreas progressively fails is at the heart of T2D. If we can protect the pancreas from failing, we can halt the progression of T2D. Today's results show for the first time the potential of GLP1 PGTx to meaningfully improve blood glucose and weight when compared to the current standard of care pharmacology," said Dr. Harith Rajagopalan, CEO of Fractyl Health. "Our goal at Fractyl Health is to eliminate T2D for the millions of people living with the disease, and these results take us one step closer to that goal."

Fractyl's PGTx is progressing through lead optimization and IND-enabling toxicity studies with the aim of first-in-human studies in 2024.

About Fractyl Health

Fractyl Health is focused on pioneering new approaches to the treatment of T2D. Despite advances in treatment over the last 50 years, metabolic diseases in general, and T2D, in particular, continue to be a principal and rapidly growing driver of morbidity and mortality in the 21st century. Fractyl Health's goal is to transform T2D treatment from chronic blood glucose management to disease-modifying therapies that target the organ-level root causes of the disease. Fractyl Health is a private organ-editing metabolic therapeutics company based in Lexington, MA. For more information, visit www.fractyl.com or www.twitter.com/FractylHealth

About Rejuva®

Fractyl Health's Rejuva® platform focuses on developing next-generation adeno-associated virus (AAV)-based, locally delivered gene therapies for the treatment of T2D and other metabolic diseases. The Rejuva platform is in preclinical development and has not yet been evaluated by regulatory agencies for investigational or commercial use. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas. The program aims to transform the management of metabolic diseases by offering novel, disease-modifying therapies that address the underlying root causes of disease.

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