



## Fractyl Announces First-Ever Commercial Availability of Revita for Type 2 Diabetes in Partnership with Leading UK Private Clinic

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LEXINGTON, Mass., January 28, 2020 — Fractyl Laboratories Inc. ([fractyl](#)) today announced its first commercial partnership with HCA Healthcare UK (United Kingdom), making its Revita® treatment commercially available for the first time for patients with type 2 diabetes. HCA Healthcare UK is the largest provider of privately funded healthcare in the UK and is part of the US-based HCA Healthcare, the world's largest private hospital group.

Revita is a first-in-class intervention designed to target insulin resistance and metabolic disease progression by resetting key pathways in the gut that drive metabolic disease. This minimally-invasive, outpatient, endoscopic procedure is a non-drug and non-surgical alternative that has been shown in clinical trials to enhance insulin sensitivity, lower HbA1c, and reduce liver fat to create long-lasting improvements in both blood sugar control and fatty liver disease to help patients with type 2 diabetes avoid further medication escalation.<sup>1</sup>

"Our first commercial market in the UK represents a significant milestone for Fractyl. It demonstrates our evolution from developing the initial science and clinical evidence behind Revita to an organization now also focused on accelerating its availability for patients with type 2 diabetes who are seeking alternatives to current approaches," said Harith Rajagopalan, M.D. Ph.D, co-founder and CEO of Fractyl. "This commercial availability is supported by data from several multinational clinical studies in hundreds of patients showing significant and sustained metabolic benefits from a single Revita DMR treatment."

"We are excited to be the first medical facility in the world to be able to offer the Revita procedure to our patients with type 2 diabetes," said Miranda Dodd, CEO of The Princess Grace Hospital, part of the HCA Healthcare UK network where the Revita procedure will be performed. "Led by a specialist team of experts, our hope is that Revita will allow patients all over the UK – and internationally – to take back control of their lives with a single treatment."

"HCA Healthcare UK is an ideal inaugural hospital system partner in the UK market. HCAs focus on bringing pioneering treatments to market aligns with Fractyl's commitment to improving the health of patients suffering from metabolic diseases. We are thrilled with the strong support from physicians as well as the collaboration with HCAs key stakeholders in making Revita available to their patients," said Margaret Borys, Chief Commercial Officer of Fractyl. "This partnership and UK commercial availability represents an important first step in bringing Revita to patients around the world."

The commercial launch of Revita in the UK comes following a series of global clinical trials on the procedure, involving close to 300 patients at over 20 centers across three continents. The research published to date shows five important metabolic benefits for patients: improved overall insulin sensitivity, lowered HbA1c (by nearly 1%), weight loss, improved liver health (more than 35% reduction in liver fat, a key factor in the development of NAFLD/NASH) and increased 'good' (HDL) cholesterol (a parameter that correlates with a reduction of CV risk).<sup>2</sup> Furthermore, reductions in HbA1c and liver fat were observed through 24 months of follow-up from a single outpatient Revita DMR procedure, indicating the potential for Revita DMR to offer durable improvements in both type 2 diabetes and NAFLD/NASH for a full two years thus far.<sup>3</sup> Revita DMR has been shown to be safe and well tolerated with no long term adverse events in clinical studies to date.

### About Type 2 Diabetes in the U.K.

Type 2 diabetes is a progressive disease, which can cause complications such as heart disease, stroke, liver and kidney damage. There are 3.8 million people living with type 2 diabetes in the UK, and the number diagnosed has more than doubled over the last 20 years.<sup>4</sup> People with type 2 diabetes may attempt to control blood glucose levels with lifestyle changes and medications, but when these are ineffective, patients may face daily insulin injections. Patients who are looking for alternatives to adding more daily medications, including insulin,<sup>5</sup> may find that Revita DMR offers a unique, non-drug alternative with compelling benefits beyond blood sugar control.

### About HCA Healthcare UK

HCA Healthcare UK includes London Bridge Hospital, The Portland Hospital, The Harley Street Clinic, The Lister Hospital, The Princess Grace Hospital, The Wellington Hospital, Roodlane Medical Ltd, and Blossoms Healthcare. HCA UK also partners with leading NHS Trusts to provide care at The Christie Private Care, HCA UK at University College Hospital and Private Care at Guy's. For more information, visit [www.hcahealthcare.co.uk](http://www.hcahealthcare.co.uk).

## **About Fractyl and Revita® DMR**

Fractyl Laboratories is a private biotechnology company based in Lexington, Mass. Fractyl is developing Revita DMR, a same-day, minimally invasive procedural therapy to treat highly prevalent metabolic diseases. The Revita DMR procedure harnesses breakthrough insights in intestinal biology and leverages the body's inherent regenerative capacity to reverse insulin resistance and metabolic diseases. Fractyl's approach aims to improve the health of patients with metabolic diseases with device-based interventions for patients and healthcare systems. The Revita DMR System received a CE mark in the European Union in April 2016. It is approved for investigational use only by the Food and Drug Administration in the United States. The Revita DMR System may be available for investigational use in other regions. For more information, visit [www.fractyl.com](http://www.fractyl.com) or [www.twitter.com/FractylLabs](https://www.twitter.com/FractylLabs).

<sup>1</sup> Van Baar, et al. [Gut](#), 2020; 69:295-303.

<sup>2</sup> Rajagopalan, et al. [Diabetes Care](#), 2016; 39:2254-2261.

<sup>3</sup> Fractyl, [Diabetes Technology Meeting](#), 2019.

<sup>4</sup> <https://www.gov.uk/government/publications/health-matters-preventing-type-2-diabetes/health-matters-preventing-type-2-diabetes>

<sup>5</sup> <https://www.england.nhs.uk/diabetes/diabetes-prevention/>

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