Topline results from REVITA-2: The first randomized, double-blind, sham-controlled, prospective, multicenter study of duodenal mucosal resurfacing (DMR) efficacy, safety, and impact on NASH biomarkers in T2D

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American Association for the Study of Liver Diseases
11 November 2019
Disclosures

JGMB received research support from Fractyl Laboratories Inc for IRB-based studies and received a consultancy fee for a single advisory board meeting of Fractyl Laboratories Inc in September 2019. JD has received research support from Fractyl Laboratories Inc for IRB approved studies. DH has received honorarium for consultancy and/or speaker fees from Novo Nordisk, Sanofi, Astra Zeneca, Roche, Sunovion, and Fractyl Laboratories Inc. EGHDM has received honorarium for consultancy from Olympus do Brasil and Boston Scientific. HR, JCLT, KW, and VB are full-time employees of Fractyl Laboratories Inc, and may hold Fractyl stock and/or stock options. GM has received funding/grant support from Novo Nordisk, Fractyl Laboratories Inc, Metacure, Keyron Ltd, and honorarium for consultancy from Johnson & Johnson, Novo Nordisk, and Fractyl Laboratories Inc. GC has received honorarium for consultancy from Boston Scientific and Apollo and is on the advisory board for Cook Medical, Olympus, and Ethicon. RH has received funding/grant support/honorarium for consultancy from Cook Endoscopy, Pentax Europe, Medtronic, C2 Therapeutics, and Fractyl Laboratories Inc to support research infrastructure. EG has received consulting fees from Fractyl Laboratories Inc, Apollo Endosurgery, and Medtronic. MG has received honorarium for consultancy from Fractyl Laboratories Inc, GI Windows, GI Dynamics, Apollo, and for speaker board from Ethicon, Medtronic, and Olympus. GPA has been a consultant and advisory board member for Agios Pharmaceuticals Inc, AstraZeneca, GlaxoSmithKline, and Pfizer. AR has received grant support from Norgine, Fujifilm, Boston Scientific, and ERBE, and served as a member of Medtronic, Boston Scientific, EndoStart, EndoKey, Alfasigma, and Fujifilm advisory boards. BH, RB, AH, and MC have nothing to disclose. AJM has received honorarium for consultancy from Fractyl Laboratories Inc and Cook Medical. AJS has been a consultant for Conatus, Gilead, Elsevier, Echosens, Malinckrodt, Immuron, Intercept, Pfizer, Salix, Uptodate, Boehringer, Ingelheim, Novartis, Nimbus, Nitto Denko, Hemoshear, Lilly, Novo Nordisk, Fractyl Laboratories Inc, Allergan, Chemomab, Affimmune, Teva, Ardelyx, Terns, ENYO, Birdrock, Albireo, Sanofi, Janssen, Takeda, Zydus, BASF, Amra, Perspectum, OWL, Poxel, Servier, Second Genome, General Electric, and 89Bio; is a stock/shareholder at Exhalenz Stock, Akarna, Durect, Indalo, and Tiziana; and received grant/research support from Novartis, Merck, Galectin, Bristol Myers, Merck, Sequana, Boehringer Ingelheim, Echosense, Salix, Malinckrodt, Cumberland, and Gilead.

Fractyl Laboratories Inc participated in the study design; study research; collection, analysis, and interpretation of data; and writing, reviewing, and approving this presentation. All authors had access to the data; participated in the development, review, and approval of the presentation for the American Association for the Study of Liver Diseases. Fractyl funded the research for this study and provided writing support for the abstract and oral presentation. Medical writing assistance, funded by Fractyl, was provided by Caroline Cazares, PhD, of JB Ashtin.
Introduction

• Novel, disease-modifying approaches are needed to treat insulin resistance–related metabolic diseases (eg, NAFLD/NASH and T2D)

• The **duodenum** is a key metabolic signaling center and critical regulator of metabolic homeostasis¹

  • High-fat and sugar diets cause hyperplasia of duodenal lining, altering hormonal signaling and nutrient absorption from the duodenum, which can lead to abdominal obesity, insulin resistance, impaired glucose metabolism, hyperinsulinemia, dyslipidemia, and high blood pressure²

  • Duodenal bypass surgery (eg, RYGB) reverses metabolic disease³: NAFLD/NASH⁴, T2D⁵,⁶, PCOS⁷,⁸, often co-existing in the same patient

• Targeting duodenal mucosal hyperplasia is a potential therapeutic option for treating insulin resistance–related metabolic diseases¹

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DMR: A novel, minimally invasive, outpatient, upper endoscopic procedure

- Revita® DMR catheter is designed to perform submucosal lift and hydrothermal ablation of hyperplastic duodenal mucosa, promote healthy epithelial regrowth within 12 weeks, and reduce insulin resistance and hyperinsulinemia\(^1,2\)


DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.
DMR: A novel, minimally invasive, outpatient, upper endoscopic procedure

- DMR is a well-tolerated procedure with few, self-limited side effects³⁻⁵

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DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.
DMR: A novel, minimally invasive, outpatient, upper endoscopic procedure

- DMR is a well-tolerated procedure with few, self-limited side effects\textsuperscript{3-5}
- Prior studies (eg, REVITA-1) showed a single DMR procedure durably improves hepatic and glycemic parameters through 2 years in patients with T2D, indicating potential benefit in T2D with concomitant NAFLD/NASH\textsuperscript{3-6}


DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.
**REVITA-2: **Prospective, sham-controlled study of the effect of DMR on hepatic and glycemic parameters in patients with sub-optimally controlled T2D across 11 sites (9 in EU, 2 in Brazil)

### Objective
Demonstrate DMR efficacy and safety compared with sham for the treatment of suboptimally controlled T2D

### Key Inclusion Criteria
- Aged 28 – 75 years
- T2D with evidence of preserved insulin secretion (fasting insulin > 7.0 μU/ mL)
- HbA1c 7.5 – 10%
- BMI ≥ 24 and ≤ 40 kg/m²
- On ≥ 1 oral antidiabetic medication (≥ 1 must be metformin)
- No medication or dose changes 12 weeks prior to study entry
- Able to comply with study and understand/sign informed consent

### Key Exclusion Criteria
- Current use of insulin or GLP-1
- History of severe hypoglycemia
- Known autoimmune disease
- Active *H. pylori* infection
- Previous GI surgery (including bariatric)
- Participating in another ongoing clinical trial of an investigational drug or device

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Data on File, Fractyl Laboratories Inc.
BMI = body mass index; GI = gastrointestinal; GLP-1 = glucagon-like peptide-1; HbA1c = hemoglobin A1c; T2D = type 2 diabetes.
REVITA-2: Study design

Screening

Med run-in (4 weeks)

Randomization 1:1

Endoscopic evaluation & treatment

OADs constant

Week:

0 12 24

(Baseline)

DMR

Sham

Data on File, Fractyl Laboratories Inc.

AESI = adverse event of special interest; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BG = blood glucose; BMI = body mass index; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; OAD = oral antidiabetic medication; SAE = serious adverse event; T2D = type 2 diabetes; UADE = unanticipated adverse device effects.
**REVITA-2: Study design**

**Screening**

- **Med run-in** (4 weeks)
  - **DMR**
  - **Sham**

**Primary endpoints**
- Absolute change in liver MRI-PDFF from baseline at 12 weeks (in patients with MRI-PDFF > 5% at baseline)
- Change in HbA1c from baseline
- Incidence rates of device/procedure-related SAEs, UADEs, and AESIs through 24 weeks

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Data on File, Fractyl Laboratories Inc.

AESI = adverse event of special interest; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BG = blood glucose; BMI = body mass index; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; OAD = oral antidiabetic medication; SAE = serious adverse event; T2D = type 2 diabetes; UADE = unanticipated adverse device effects.
REVITA-2: Study design

**Primary endpoints**
- Absolute change in liver MRI-PDFF from baseline at 12 weeks (in patients with MRI-PDFF > 5% at baseline)
- Relative change from baseline in liver MRI-PDFF in patients with MRI-PDFF > 5% at baseline

**Selected secondary endpoint**
- Change in HbA1c from baseline
- Incidence rates of device/procedure-related SAEs, UADEs, and AESIs through 24 weeks

Data on File, Fractyl Laboratories Inc.

AESI = adverse event of special interest; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BG = blood glucose; BMI = body mass index; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; OAD = oral antidiabetic medication; SAE = serious adverse event; T2D = type 2 diabetes; UADE = unanticipated adverse device effects.
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**REVITA-2 statistical methods: How success was defined in SAP**

- **Assessment of normality**
- **Assessment for homogeneity**
- **mITT analysis**

**Brazil not homogeneous to European countries in hepatic and glycemic endpoints, regardless of treatment group**

**Prespecified interaction statistical test assessed homogeneity across geographic regions**

**Brazilian and European populations not poolable, analyses were stratified, and mITT results separated by region**

- **Both HbA1c and liver MRI-PDFF primary endpoints = p < 0.05**
- **1 of 2 primary endpoints = p < 0.025**

DMR = duodenal mucosal resurfacing; mITT = modified intent to treat; MRI-PDFF = magnetic resonance imaging proton density fat fraction; SAP = statistical analysis plan.

Data on File, Fractyl Laboratories Inc.
**REVITA-2: Patient disposition**

**Enrollment**

**Randomized, n = 108**

**EU, n = 76**

- **DMR, n = 39**
  - Discontinuation, n = 1
  - Analyzed, n = 39
    - mITT (n = 39)
    - PP (n = 35)
    - Safety (n = 39)

- **Sham, n = 37**
  - Discontinuation, n = 2
  - Analyzed, n = 37
    - mITT (n = 36)
    - PP (n = 36)
    - Safety (n = 37)

**Brazil, n = 33**

- **DMR, n = 17**
  - Discontinuation, n = 0
  - Analyzed, n = 17
    - mITT (n = 17)
    - PP (n = 13)
    - Safety (n = 17)

- **Sham, n = 16**
  - Discontinuation, n = 1
  - Analyzed, n = 16
    - mITT (n = 16)
    - PP (n = 16)
    - Safety (n = 16)

Data on File, Fractyl Laboratories Inc.
DMR = duodenal mucosal resurfacing; EU = European Union; mITT = modified intent to treat; PP = per-protocol.
**REVITA-2: Patient demographics and baseline characteristics (mITT)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>EU</th>
<th>Brazil</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>DMR (N = 39)</strong></td>
<td><strong>Sham (N = 36)</strong></td>
<td><strong>DMR (N = 17)</strong></td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
<td>59.0 (40.0, 72.0)</td>
<td>56.5 (35.0, 75.0)</td>
<td>0.62</td>
</tr>
<tr>
<td><strong>Male, n (%)</strong></td>
<td>30 (76.9)</td>
<td>28 (77.8)</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
<td></td>
<td>0.60</td>
</tr>
<tr>
<td>White</td>
<td>25 (64.1)</td>
<td>21 (58.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (2.6)</td>
<td>3 (8.3)</td>
<td></td>
</tr>
<tr>
<td>Undisclosed</td>
<td>13 (33.3)</td>
<td>12 (33.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Weight, kg</strong></td>
<td>93.1 (64.8, 155.0)</td>
<td>94.5 (66.6, 113.4)</td>
<td>0.66</td>
</tr>
<tr>
<td><strong>BMI, kg/m²</strong></td>
<td>31.4 (23.6, 39.5)</td>
<td>30.4 (24.2, 39.6)</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Liver MRI-PDFF, % &gt; 5% at baseline, n (%)</strong></td>
<td>16.5 (5.5, 33.0)</td>
<td>16.1 (5.6, 33.8)</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>ALT, U/L</strong></td>
<td>31.0 (11.0, 76.0)</td>
<td>29.0 (12.0, 162.0)</td>
<td>0.65</td>
</tr>
<tr>
<td><strong>AST, U/L</strong></td>
<td>21.0 (11.0, 44.0)</td>
<td>19.5 (10.0, 131.0)</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>Fasting glucose, mg/dL</strong></td>
<td>191.0 (122.0, 313.0)</td>
<td>185.5 (110.0, 344.0)</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>HbA1c, %</strong></td>
<td>8.1 (7.5, 10.0)</td>
<td>8.2 (7.5, 10.0)</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>C-peptide, ng/mL</strong></td>
<td>2.5 (0.7, 4.9)</td>
<td>2.3 (1.5, 5.0)</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>Fasting insulin, mU/L</strong></td>
<td>9.8 (2.4, 22.6)</td>
<td>8.4 (3.9, 17.6)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

mITT population data for continuous variables are presented as median (min, max), unless otherwise noted.

*p values are from Mann-Whitney U test for continuous variables due to non-normality and chi-squared test (or Fisher’s exact test when appropriate) for categorical variables, unless otherwise specified. If the baseline value was missing for a given variable and patients, the screening value was used in its place prior to calculating the descriptive statistics. All p values are two-sided.

mITT population defined as all randomized subjects in whom the study procedure (DMR or sham) is attempted and who have a baseline measurement for at least one primary endpoint.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; BMI = body mass index; DMR = duodenal mucosal resurfacing; HbA1c = hemoglobin A1c; MRI-PDFF = magnetic resonance imaging proton density fat fraction.
## REVITA-2: Favorable safety profile through 24 wks post-DMR

<table>
<thead>
<tr>
<th>Summary of device-/procedure-related</th>
<th>EU</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DMR (N = 39)</td>
<td>Sham (N = 36)</td>
</tr>
<tr>
<td><strong>SAE, n (%)</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>UADE, n (%)</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>AESI, n (%)</strong></td>
<td>13 (33.3)</td>
<td>10 (27.0)</td>
</tr>
</tbody>
</table>

### Most common (≥ 5%) device-/procedure-related AESI

<table>
<thead>
<tr>
<th>Disorder</th>
<th>EU</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>11 (28.2)</td>
<td>8 (21.6)</td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>6 (15.4)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3 (7.7)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1 (2.6)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2 (5.1)</td>
<td>0</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>3 (7.7)</td>
<td>3 (8.1)</td>
</tr>
</tbody>
</table>

Data are presented as n (%), with n as the number of patients with an event. AESI = adverse event of special interest; DMR = duodenal mucosal resurfacing; SAE = serious adverse event; UADE = unanticipated adverse device effects.
REVITA-2: DMR significantly improves liver fat content

Changes in Liver MRI-PDFF in Patients with > 5% Liver Fat Content at Baseline (mITT)

Baseline median (min, max) liver MRI-PDFF: 16.1 (5.5, 35.8)

<table>
<thead>
<tr>
<th></th>
<th>DMR</th>
<th>Sham</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median absolute change from baseline at 12 weeks, %</td>
<td>-5.4</td>
<td>-2.4</td>
<td>0.039</td>
</tr>
<tr>
<td></td>
<td>n = 30</td>
<td>n = 27</td>
<td></td>
</tr>
<tr>
<td>Median relative change from baseline at 12 weeks, %</td>
<td>-32.1</td>
<td>-18.1</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>n = 30</td>
<td>n = 27</td>
<td></td>
</tr>
</tbody>
</table>

Data on File, Fractyl Laboratories Inc.

Treatment comparison one-sided p value based on ANCOVA model with Multiple Imputation on the rank values (modified ridit scores). Via multiple imputation, analysis is based on all patients in the population of interest where post-rescue values are first set to missing. ANCOVA = analysis of covariance; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction.
**REVITA-2: Exploratory hepatic analyses**

**Responder Analysis:** > 30% reduction in relative liver MRI-PDFF from baseline to week 12 (mITT)

![Responder Analysis Chart](image)

**Change in hepatic transaminases from baseline at 12 weeks**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DMR</th>
<th>Sham</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT, U/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (min, max)</td>
<td>n = 36</td>
<td>n = 36</td>
<td>0.143</td>
</tr>
<tr>
<td>-4.5 (−37.0, 13.0)</td>
<td>-2.0 (−36.0, 43.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST, U/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (min, max)</td>
<td>n = 32</td>
<td>n = 31</td>
<td>0.117</td>
</tr>
<tr>
<td>-1.5 (−18.0, 9.0)</td>
<td>-1.0 (−37.0, 12.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as median (min, max). One-sided \( p \) value based on ANCOVA model on the rank values (modified ridit scores) in mITT population for change from baseline to 12 weeks DMR vs. sham. ALT = alanine aminotransferase; AST = aspartate aminotransferase; DMR = duodenal mucosal resurfacing.

Large magnitude and clinically meaningful reductions in liver fat content

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Data on File, Fractyl Laboratories Inc.

MRI-PDFF treatment comparison (DMR vs. SHAM) one-sided \( p \) value from chi-square test with no imputation of missing data and values post-rescue medication are set to missing. DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction.
REVITA-2: DMR positively impacts glucose metabolism

Change in HbA1c from baseline to 24 weeks

Responders Analysis: HbA1c (mITT)

Baseline median (min, max) HbA1c: 8.1 (7.5, 10.0)

-0.6 (mITT, n = 38) p = 0.033

-0.8 (PP, n = 35) p = 0.004

Patients achieving HbA1c < 7% at 24 weeks, %

DMR: 26.3, p = 0.031
Sham: 9.1

Data on File, Fractyl Laboratories Inc.

Left panel: Treatment comparison one-sided p value based on ANCOVA model with Multiple Imputation on the rank values (modified ridit scores). Via multiple imputation, analysis is based on all patients in the population of interest. Right panel: Treatment comparison (DMR vs. SHAM) one-sided p value from chi-square test with no imputation of missing data and values post-rescue medication are set to missing. 2 people missing HbA1c at week 24; 1 person set to missing post-rescue medication = 72 people in sample of 75 Europeans (PP). Four patients in mITT excluded from PP population. DMR = duodenal mucosal resurfacing; FPG = fasting plasma glucose; HbA1c = hemoglobin A1c; PP = per-protocol.
**REVITA-2:** Significantly greater reductions in liver MRI-PDFF and HbA1c in patients with baseline FPG ≥ 180 mg/dL

Greater benefit in patients (PP) with higher FPG at baseline\(^2\) supports the role of hepatic IR in NAFLD/NASH and T2D.

1. Data on File, Fractyl Laboratories Inc.

**REVITA-2 | AASLD | November 11, 2019**
REVITA-2: Conclusions

• DMR is a novel intestinal-targeted therapy for T2D ± NAFLD with sustained response up to 6 months in this placebo-controlled study
  
  • REVITA-1 study demonstrated durable glycemic and hepatic improvements through 2 years¹

• Results from REVITA-2 validate that the duodenum is a therapeutic target and raise important mechanistic questions

• DMR is an important new option for patients with T2D ± NAFLD/NASH with focus on disease reversal rather than management, particularly considering polypharmacy burden in these patients

• DMR has a safety and tolerability profile encouraging for broad therapeutic applicability in these disease states

¹ van Baar ACG et al., DTM 2019 poster VAN 19122D. DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.