First In-Human Mesenteric Visceral Lipectomy Clinical Trial Update

July 2022

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Clinical Trial Overview

Enrollment Update

12 subjects have undergone the MVL procedure (11 complete MVL procedures and 1 partial MVL procedure)

- Subject 1 : MVL surgery 11/18/2019 – 21 of 21 Visits completed
- Subject 2 : MVL surgery 3/31/2021 – 21 of 21 Visits completed

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- Subject 3 : MVL surgery 7/14/2021 – 11 months post-op, Visit 18 completed (10 months post-op visit)
- Subject 4 : MVL surgery 8/18/2021 – 10 months post-op, Visit 18 completed (10 months post-op visit)
- Subject 5 : MVL surgery 10/13/2021 – 8 months post-op, Visit 15 completed (6 months post-op visit)
- Subject 6 : MVL surgery 11/16/2021, small bowel mass discovered after mesenteric fat had been removed from 1/5th of the length of the small bowel, fat extraction starting at proximal jejunum – *subject dropped from study* (section of small bowel resected; mass was benign)
- Subject 7 : MVL surgery 11/17/2021 – 7 months post-op, Visit 13 completed (4.5 months post-op visit); TDI is continuing to make attempts to contact subject

Overview - continued

- Subject 8 : MVL surgery 11/17/2021 – 7 months post-op, Visit 13 completed (4.5 months post-op visit); subject has moved to Colorado and will return to TDI for 6 months post-op visits on July 8, 2022
- Subject 9 : MVL surgery 2/9/2022 – 4 months post-op, Visit 12 (in mid May) completed (12 weeks post-op visit) *just for safety - on Visit 11 (in early April) ~ 2 months after undergoing MVL surgery, the subject was dropped from the study for efficacy because a diagnosis of antiphospholipid syndrome was made by a rheumatologist. The subject was started on prednisone - Visit 12 (in mid May) subject is doing well and has no complaints*
- Subject 10 : MVL surgery 4/25/2022 – 10 weeks post-op, Visit 8 completed (3 weeks post-op visit); subject moved to Colorado and will return on July 8, 2022 for next study visit (Subject 8 and 10 are husband and wife)
- Subject 11 : MVL surgery 5/31/2022 – 4 weeks post-op, Visit 9 completed (4 weeks post-op visit)
- Subject 12 : MVL surgery 5/31/2022 – 4 weeks post-op, Visit 9 completed (4 weeks post-op visit)

CLINICAL TRIAL OVERVIEW
On-going Initiatives

- Following 11 for safety; 10 for efficacy
- An IDE supplement was submitted to the FDA on June 14 requesting to increase the cohort size up to 14 (two additional subjects) to ensure that enough data is collected in case the final cohort who complete the Trial is less than 10 subjects.
- The FDA and the University of Texas Health Science Center San Antonio IRB approved an extension of the study for subjects who had 70% of mesenteric visceral fat removed. Such subjects will be invited for follow-up tests for an additional 24 months upon the end of initial 12 month follow-up (5 additional visits at 18, 24 and 36 months post-op).

Efficacy Results to Date

EARLY EFFICACY ANALYSIS in 7 subjects

(subjects 1,2,3,4,5,7 and 8; based on data from 4.5 months to 12 months post-op)

- The 2 subjects, 1 and 3, who had the least amount of fat removed, less than 50%, have had minimal to no improvement in glycemic control
- 4 subjects (subjects 2, 4, 7 and 8) who had greater than 60% of fat removed have had significant improvement in glycemic control over varying amounts of time
- While subject 5 had only 50% of fat removed he/she continued to show improvement in glycemic control up to 6 months post procedure
- Subject 3 had the *least amount of fat removed* (250 ml measured in canister; V/L Ratio 40) and has had *the least improvement* in glycemic control; Subject 8 had the *most amount of fat removed* (600 ml measured in the canister; V/L Ratio 130) and has had the *most improvement* in glycemic control

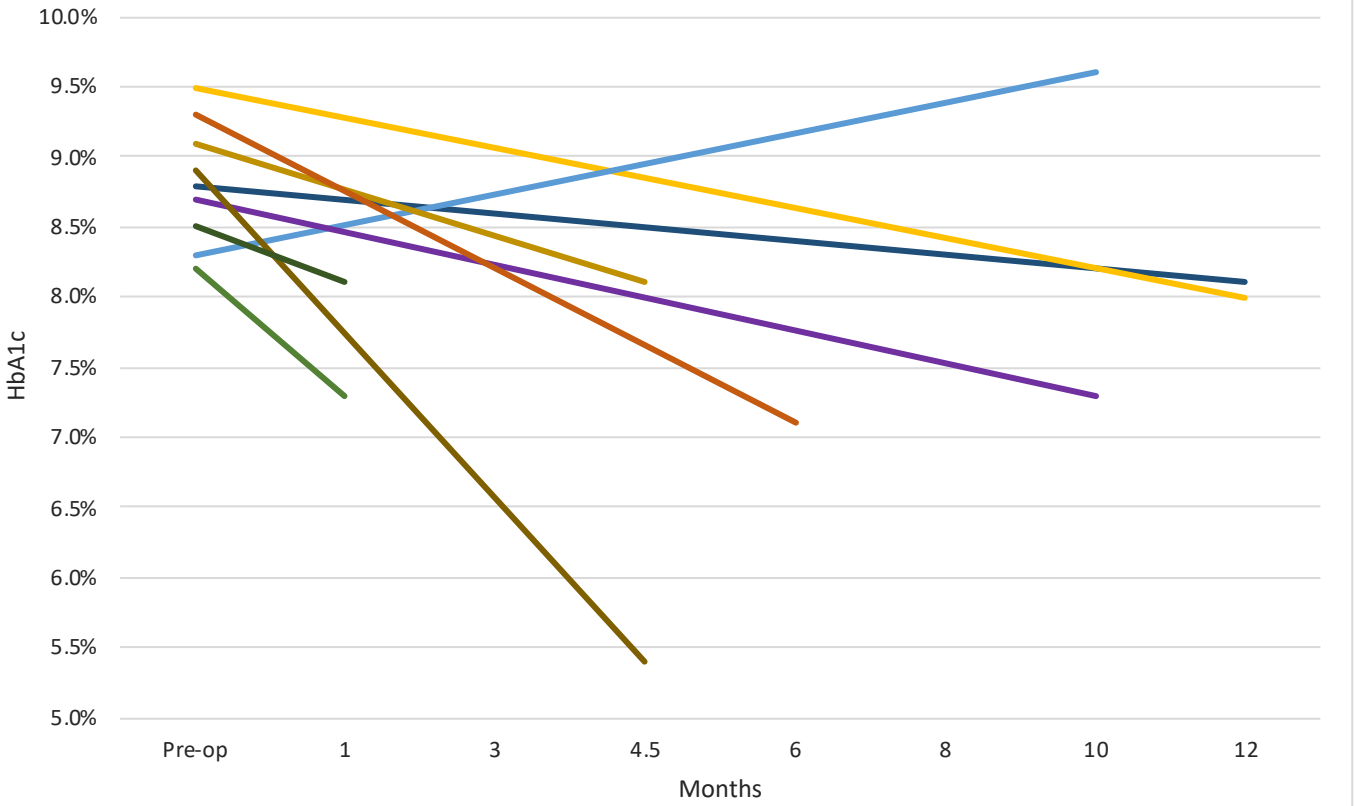
Blood Glucose Levels

		Normal	Prediabetes	Diabetes	Notes
HbA1C	Hemoglobin A1c	<5.7	5.7 - 6.4	>6.5	HbA1c is a measure of how well controlled your blood sugar has been over a period of about 3 months. The term HbA1c refers to glycated hemoglobin.
FPG	Fasting Plasma Glucose	< 100 mg/dL	100 to 125 mg/dL	≥ 126 mg/dL	The fasting plasma glucose (FPG) test indicates blood sugar levels after a fasting period where an individual has not had anything to eat or drink, except water, for the previous 8 to 12 hours. Fasting plasma glucose is synonymous with fasting blood sugar
CGM TIR	Continuous Glucose Monitoring - Time in Range	n/a	n/a	n/a	% of time blood glucose level is within range. The target is 70% meaning 17 hours out of 24 hrs each day should be between 70 and 180 mg/dL.

Glycemic Control of 7 subjects

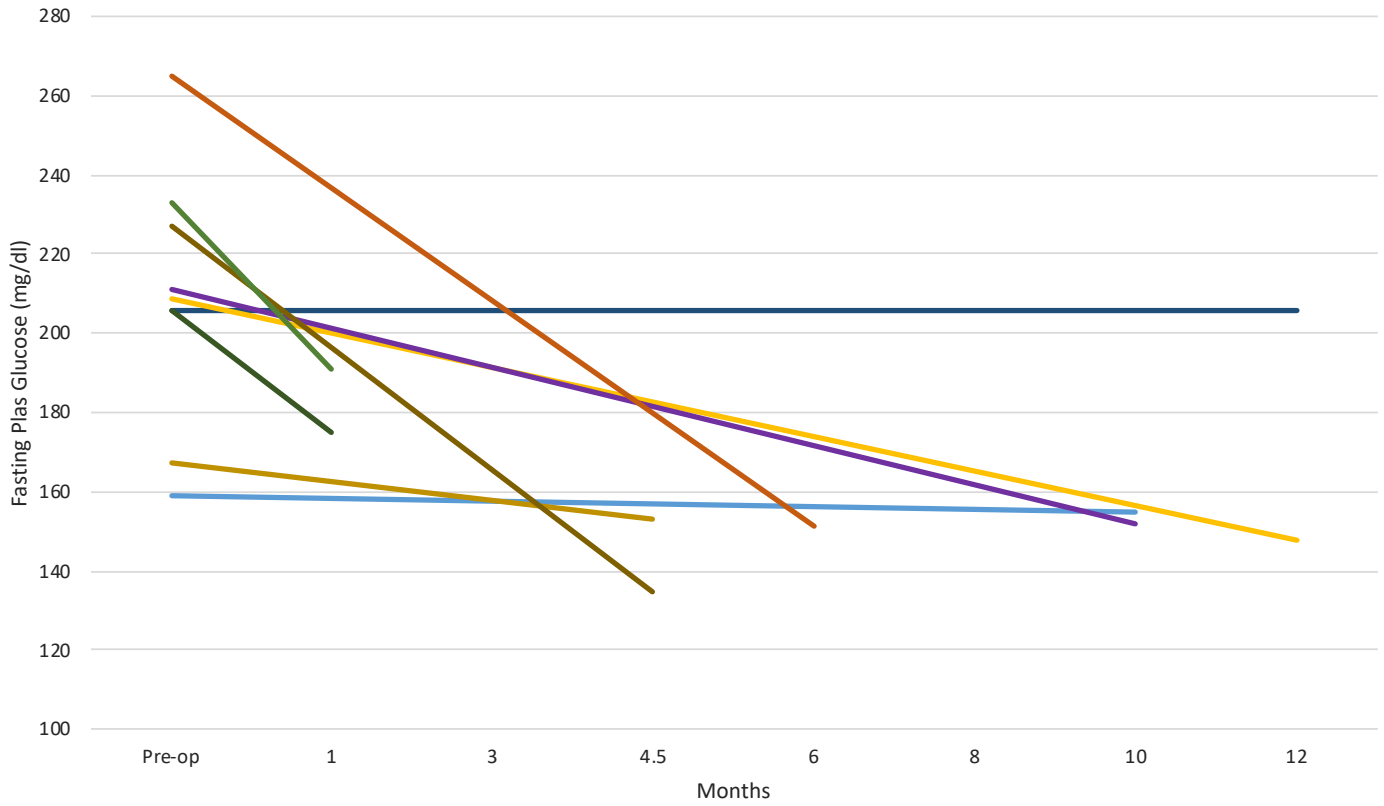
(at least 4.5 months after MVL procedure)

Subject	1	2	3	4	5	7	8	AVG
Months after MVL	12	12	10	10	6	4.5	4.5	
HbA1c % change	-0.7	-1.5	+1.3	-1.4	-2.2	-1.0	-3.5	-1.2
FPG mg/ml change	0	-61	-4	-59	-114	-14	-92	-49
TIR % change	+6	+70	+19	+54	+64	+8	+88	+44

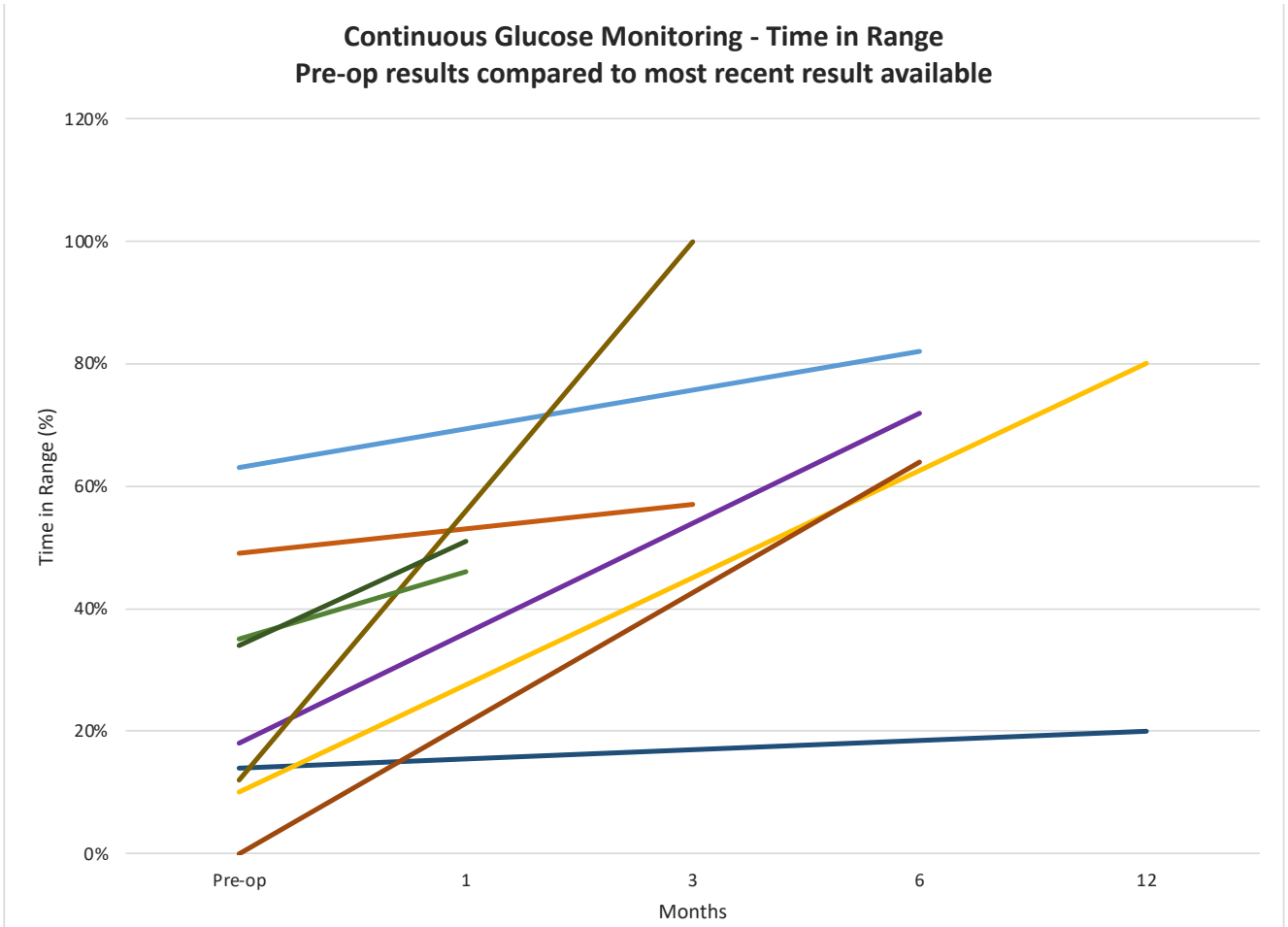


	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 7	Subject 8	Subject 11	Subject 12
% fat removed	30%	60%	50%	60%	50%	70%	80%	80%	75%
V/L	n/a	80	40	60	70	90	130	80	70
A1c Change	-0.7%	-1.5%	1.3%	-1.4%	-2.2%	-1.0%	-3.5%	-0.9%	-0.4%
Months after MVL	12mos	12mos	10mos	10mos	6mos	4.5mos	4.5mos	1mo	1mo

Fasting Plasma Glucose Chart
Pre-op results compared to most recent result available



	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 7	Subject 8	Subject 11	Subject 12
% fat removed	30%	60%	50%	60%	50%	70%	80%	80%	75%
V/L	n/a	80	40	60	70	90	130	80	70
FPG change	0	-61	-4	-59	-114	-14	-92	-42	-31
Months after MVL	12mos	12mos	10mos	10mos	6mos	4.5mos	4.5mos	1mo	1mo



	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 7	Subject 8	Subject 11	Subject 12
% fat removed	30%	60%	50%	60%	50%	70%	80%	80%	75%
V/L	n/a	80	40	60	70	90	130	80	70
TIR change	6%	70%	19%	54%	64%	8%	88%	11%	17%
Months after MVL	12mos	12mos	6mos	6mos	6mos	3mos	3mos	1mo	1mo

Glycemic control improvement of top 5 out of 7 subjects

Based on amount of visceral fat removed (Subjects 2, 4, 5, 7 and 8)

- AVERAGE HbA1c reduction: **1.9** percentage points
- AVERAGE FPG reduction: **66** mg/dl
- AVERAGE TIR increase: **57** percentage points

SUMMARY EVALUATION
Clinical Trial

No major adverse events have occurred in the clinical trial to date, except one, subject 1, who had a mild case of Ileus, was hospitalized one night and released without further complications.

The majority of subjects continue to show improvement in the glycemic control of their T2D as of their last visits which vary in time.

Anastassia Amaro MD, a University of Pennsylvania endocrinologist and the Company's advisor states *"the interim analysis of the MVL procedure demonstrates safety and early efficacy which I find very encouraging for patients suffering from Type 2 diabetes"*