

A randomized, double-blind, placebo-controlled, parallel, research study to investigate the safety and efficacy of a probiotic *Lactobacillus plantarum* 276 (Lp 276) on gastrointestinal health in healthy adults

FINAL STUDY REPORT

2 EXECUTIVE SUMMARY

Highlights:

- No significant differences between the *Lactobacillus plantarum* 276 (Lp 276) supplementation and placebo were identified in this pilot clinical study. Potential underlying factors include but may not be limited to: impact of the COVID-19 pandemic on physiological and psychological status of the study population; small sample size, high placebo effect for the type of studies with otherwise healthy individuals who are not at disease state to detect significant differences, subjective nature of assessments and impact of diet on the outcome.
- There were statistically significant improvements within the Lp 276 group which are considered potential benefits for further consideration:
 - Supplementation with Lp 276 significantly improved gastrointestinal symptoms above baseline related to diarrhea including urgent need for defecation at Day 7, 14, 21 and 28 and loose stools at Day 14, 21 and 28.
 - Participants in the Lp276 group had significant improvements in experiencing abdominal discomfort after meals, having a hard time tolerating foods and feeling physically strong (≤ 0.037). None of these beneficial changes were reported by the placebo group.
 - Participants in the Lp 276 group had an average 8.1% increase in the proportion of stools with normal consistency ($p=0.038$) and there was a significant decrease in the proportion of participants' bowel movements that were diarrhea (BSS type 5-7) by Day 14.
 - There were significant improvements in heartburn at Days 14 and 28 with Lp 276 supplementation ($p=0.025$).