Synopsis Galaxy study

G3P-01 is an investigational pectin extracted, enriched and purified from commercial squash puree intended for human consumption. Pectins are an important constituent of fruits and vegetables, and health benefits are attributed to its intake. Some of the health benefits of pectins are attributed to inhibition of galectin-3. This study investigated tolerability of 30-days G3P-01 intake, and whether 30-days of G3P-01 intake induces biomarker changes that can be attributed to target engagement. This was a double-blind randomized placebo-controlled dose ranging study. Human volunteers with previously elevated galectin-3 levels (\geq 16.0 ng/mL), aged \geq 45 and \leq 75 years were randomized into four groups (placebo, 100mg, 250mg and 1000mg G3P-01).

This report contains the evaluation of tolerability of G3P-01 as determined by emerging signs or symptoms, laboratory safety parameters (change from baseline or emergence of clinically significant abnormal values) and the Gastrointestinal Symptom Rating Scale (GSRS). No concerns regarding tolerability were raised based on this study. No significant changes were observed on laboratory measurements. Proteomics analysis will be performed in a later stage.