Official Protocol Title: A Phase 2 Proof-of-Concept Study of Sensor-Guided, Clinician-Administered Delivery of G-Pump™ (Glucagon Infusion) From an OmniPod® to Prevent Post-Prandial Hypoglycemia in Post-Bariatric Surgery Patients

NCT02733588

Document Date: February 13, 2017

Statistical Analysis Plan for Protocol XSGO-PB01

Analysis Population. Participants with a history of RYGB surgery and PBH with neuroglycopenia, uncontrolled on medical nutrition therapy and medications, were recruited from the hypoglycemia clinic. Exclusion criteria included fasting hypoglycemia, known insulinoma, major systemic illness, pregnancy, substance or alcohol abuse, recent steroid or investigational drug exposure, and use of medications (beyond hypoglycemia treatment) known to affect insulin secretion or action. The Joslin Diabetes Center Committee on Human Studies approved the study. Written informed consent was obtained from all participants. Six females and one male were enrolled. Two participants enrolled twice, in different stages of system development. All enrolled participants were included in the analysis.

Study endpoints. This iterative development clinical study was designed to evaluate the primary endpoints of safety and feasibility of the proposed system to predict and prevent severe hypoglycemia in patients with PBH. Secondary outcomes included prediction of imminent hypoglycemia by the automatic monitoring algorithm, minimization of time below a prespecified threshold (<75 mg/dL) using glucagon delivery, prevention of severe postprandial hypoglycemia (plasma glucose <60 mg/dL), and prevention of rebound hyperglycemia (plasma glucose >180 mg/dL) after glucagon delivery.

Statistics. As an algorithm iterative development study, sample size was not determined by a power calculation. Statistical analyses were performed using GraphPad Prism (GraphPad Software, La Jolla, CA). Normally distributed data were expressed as mean ± standard deviation and skewed data were expressed as median with interquartile range. Normality was determined using the Shapiro-Wilk test[1]. Statistical significance was determined with the Wilcoxon signed-rank test[2].

References.

1. Shapiro SS, Wilk MB. An analysis of variance test for normality (complete samples). *Biometrika* 1965; **52**: 591–611.
2. Wilcoxon F. Individual Comparisons by Ranking Methods. *Biom Bull* 1945; **1**: 80–3.