PENNSTATE HERSHEY
Milton S. Hershey Medical Center

**STUDY TITLE:** A Phase II, Double-Blind, Placebo-Controlled, Dose Finding Study to Evaluate the Safety and Efficacy of Ipamorelin Compared to Placebo for Recovery of Gastrointestinal Function in Patients Following Small or Large Bowel Resection with Primary Anastomosis

**PRIMARY STUDY OBJECTIVE:** To assess the efficacy of Ipamorelin verses placebo on the recovery time of gastrointestinal (GI) function in partial small and/or large bowel resection patients, measured by time to first toleration of solid food and time to first bowel movement.

**INCLUSION CRITERIA:** Male or female, 18 to 85 years, due to undergo a scheduled small and/or large partial bowel resection, body weight between 88 lbs – 330 lbs (40-150 kilograms).

**EXCLUSION CRITERIA:** Any procedure requiring a diverting stoma; clinically unstable, significant liver or kidney disease; history of irritable bowel syndrome; patients with a history of Crohn's disease or ulcerative colitis who have had multiple GI related surgeries; patients who have had prior abdominal and/or pelvic radiation

**STUDY TREATMENT:** Patients will be randomized to receive 1 of 4 treatment arms:

- Ipamorelin 0.03 mg/kg, twice per day (2 investigational drug infusion as and 1 placebo infusion), or
- Ipamorelin 0.06 mg/kg, twice per day (2 investigational drug infusions and 1 placebo infusion), or
- Ipamorelin 0.06 mg/kg, three times per day (3 investigational drug infusions), or
- Matching placebo, three times per day (3 placebo infusions).

Patients will receive 3 infusions per day beginning post-operative day 1 through post-operative day 7 or hospital discharge whichever comes first. 14 days after surgery patients return to the clinic for their final study visit.
Compensation will be provided.

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This study has received IRB approval from the Human Subjects Protection Office at Penn State Milton S. Hershey Medical Center, and the Penn State College of Medicine 600 Centerview Drive, PO Box 855, MC: A115, Hershey PA 17033. IRB# 35691