

# ESPEN 2019 Abstract Submission

**Topic:** *Liver and gastrointestinal tract*

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## EFFECT OF APRAGLUTIDE, A GLUCAGON-LIKE PEPTIDE-2 ANALOG, ON PATIENTS WITH SHORT BOWEL SYNDROME: PRELIMINARY RESULTS FROM AN OPEN-LABEL STUDY

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**If you think another topic than the one selected at first would suit your abstract, please choose below.:** Nutrition and chronic diseases

**Rationale:** Treatment with glucagon-like peptide (GLP)-2 and its analogs have been shown to improve intestinal function in patients with short bowel syndrome (SBS). This study investigates the safety and efficacy of weekly dosing of apraglutide, a novel long-acting GLP-2 analog, in development for the treatment of SBS.

**Methods:** A total of 8 patients will be enrolled in an open-label phase II trial with a 5 mg once-weekly subcutaneous injection of apraglutide for 4 weeks. Main inclusion criteria include an average fecal output  $\geq 1500$  g/day and a urine volume  $< 2000$  ml/day. We present preliminary results from 3 patients. Safety was the primary endpoint. As secondary endpoints, we examined changes from baseline in stoma wet weight output and intestinal absorption of wet weight and energy measured by metabolic balance studies.

**Results:** Common adverse events (AEs) were peripheral edema, polyuria and stoma nipple enlargement. AEs were transient with a mild to moderate severity. No safety concerns were observed with laboratory values, vital signs or ECGs. We observed a decrease in stoma wet weight output and an increase in intestinal absorption of wet weight and energy (Table 1). Initial pharmacokinetic analysis supports once-weekly dosing.

**Table 1.** Results from 3-day metabolic balance studies: Change from baseline after 4 weeks of apraglutide treatment. SBL=short bowel length.

3-day average	63-year old female with jejunostomy SBL=150cm	61-year old male with jejunostomy SBL=140cm	65-year old female with jejunostomy SBL=230cm
Stoma wet weight output, g/day (%)	-1533 (-28%)	-1632 (-33%)	-280 (-15%)
Wet weight absorption, g/day (%)	1607 (+98%)	1732 (+83%)	95 (+4%)
Energy absorption, kJ/day (%)	2164 (+34%)	3038 (+37%)	388 (+5%)

**Conclusions:** Preliminary results from this open-label phase II study showed that weekly dosing of apraglutide was safe and well tolerated and improved intestinal absorption in patients with SBS.

**Disclosure of Interest:** None Declared

**Keywords:** Short bowel syndrome