

Title\_Poster\_Paper: ORAL PRESENTATION: EFFECTS OF TEDUGLUTIDE, AN ANALOG OF HUMAN GLP-2, ON INTESTINAL FLUID ABSORPTION IN SHORT BOWEL SYNDROME (SBS) PATIENTS

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Abs Title: EFFECTS OF TEDUGLUTIDE, AN ANALOG OF HUMAN GLP-2, ON INTESTINAL FLUID ABSORPTION IN SHORT BOWEL SYNDROME (SBS) PATIENTS

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Rationale: In short bowel syndrome (SBS) patients, intestinal fluid absorption (IFA) is oral intake minus faecal excretion. Faecal collections are cumbersome. As urine volume increases when intestinal fluid absorption increases, this is the preferred surrogate marker of intestinal fluid absorption, provided that oral intake and parenteral support are constant. Therefore, in clinical studies parenteral support reduction algorithms based on increase in urine volume have been used to reflect increase in intestinal fluid absorption. The Fluid Composite Effect (FCE) (= parenteral solution volume + oral intake – urine volume), provides a better description of the combined overall effects. Teduglutide has been suggested to improve intestinal fluid absorption. This study describes teduglutide's effects on the individual components of the fluid composite effect (FCE).

Methods: 86 stable SBS subjects requiring parenteral support were randomized to s.c. teduglutide (0.05 mg/kg/d) or placebo for 24 weeks. For 48 hours prior to each 4-weekly visit, subjects recorded their oral fluid intake and urine production. Parenteral solution was reduced, if urine volume exceeded baseline by >10%.

Results: At Week 24, teduglutide 0.05 mg/kg/d reduced parenteral support volume by 4.4 l/wk (n=43; 12.9 l/wk at baseline), vs. placebo 2.3 l/wk (n=43; 13.2 l/wk at baseline, p<0.001, ITT-population). Placebo patients increased 48 hour oral fluid intake by 452 ml, (teduglutide: reduction of 49 ml). Increase in 48 hour urine volume was 81 ml on placebo vs. 296 ml on teduglutide. Thus, evaluated by the fluid composite effect, teduglutide improved intestinal fluid absorption by +5.4 l/wk whereas the effect of placebo was +1.1 l/wk (p<0.001, ITT-population).

Conclusion: Compared to placebo, teduglutide effectively reduced parenteral support (2.1 l/wk), but its effects on intestinal fluid absorption were in fact twice as high (4.3 l/wk), when evaluating the overall fluid composite effect.

Disclosure of Interest: P. Jeppesen Other: Consultant to Nycomed and NPS Pharmaceuticals, S. Gabe Other: Consultant to Nycomed, H.-G. Lamprecht Other: Consultant to Nycomed, H. Heinze Other: Company Employee, N. Youssef Other: Company Employee, L. Pironi Other: Consultant to Nycomed

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