Revestive®
teduglutide

TIME TO RESPONSE: PREDICTORS

Time to sustained clinical response may vary for patients on REVESTIVE[1,2]

Knowing whether patients are likely to achieve an earlier response (within 24 weeks) may help set more accurate patient and physician expectations and encourage treatment persistence.[1,2]

A post-hoc analysis of STEPS and STEPS-2 identified factors associated with early versus late response[1]

Time to sustained clinical response# for patients on REVESTIVE 0.05mg/kg/day during STEPS (Week 24) or STEPS-2 (24 months)[1]

3.6 MONTHS

(1.1 SD)

Early responders to treatment (STEPS,n=27)[1**]

- 51% had colon-in-continuity
- 24.6% of colon remaining
- 0% had ileocecal valve

10.0 MONTHS

(6.1 SD)

Late responders to treatment (STEPS-2,n=7)[1**]

- All patients had colon-in-continuity
- 57.1% of colon remaining
- 28.6% had ileocecal valve

**p<0.05 for all early vs late responder comparisons
#Time to sustained clinical response defined as the period between the baseline visit of STEPS and the second consecutive visit during STEPS or STEPS-2 with PN volume reduction ≥20%.[1]
Early responders defined as patients with PS volume reduction ≥20% from baseline at both Weeks 20 and 24 in STEPS.[1]
Late responders defined as patients with sustained PS volume reduction ≥20% from baseline at any 2 consecutive visits during STEPS-2, or at both Week 24 during STEPS and Month 1 in STEPS-2.[1]

Bowel anatomy may impact time to response to REVESTIVE[1]

IBD, presence of a stoma, and absence of ileocecal valve were associated with earlier response to REVESTIVE[1]

In another post-hoc analysis of STEPS, patients with a stoma and no colon-in-continuity who had the highest PS baseline volumes (mean 14.5 L/week) achieved the largest mean PS volume reductions (–6.4 L/week) and the earliest response (significant from Week 4)[2]

A French real world study showed bowel anatomy, baseline PS volume and oral intake may predict PS reductions by week 24[3]

A French national retrospective, open-label, observational cohort study of patients with SBS-IF treated with REVESTIVE for at least 6 months (n=54)[3]

Group 1: jejunostomy or ileostomy; Group 2: ≥50% of colon -in-continuity; Group 3: <50% colon or colostomy

Results at Week 24		Group 1 (n=19)	Group 2 (n=33)	Group 3 (N=2)
PS volume change from baseline (SD)	Baseline PS volume, mL/day	2295 (344)	1197 (137)	1693 (1050)
	PS volume change, mL/day	-954 (165)*	-527 (82)	-1221 (579)
	% change from baseline	-45% (6)	-53% (7)	-83% (17)
Calories change from baseline (SD)	Baseline PS calories, kcal/day	967 (175)	876 (92)	397 (128)
	PS calories change, kcal/day	-520 (89)	-410 (63)	-283 (243)
Days off PS/week (SD)	% change from baseline	-48% (9)	-47% (7)	-57% (43)
	Baseline PS days/week	5.3 (0.4)	3.8 (0.3)	4.5 (1.5)
Responders	Days off PS/week	-1.4 (0.3)	-1.6 (3)	-3 (0)
	% responders (20-100% reduction in PS from baseline)	95%	79%	100%
Weaned off PS	Number of patients weaned	2/19	10/33	1/2
	% patients weaned	11%	31%**	50%**

*P=0.02 vs Group 2&3 **P=0.004 vs Group 1

Adapted from Joly F et al. 2020[3]

- Predictors of higher absolute reduction in PS volume at week 24 are a higher baseline oral intake (p=0.045) and a higher basal PS volume (p<0.001).
- Predictive factors for response at week 24 are: higher baseline oral intake (p=0.02)
- Predictors of PS withdrawal by week 24 are presence of colon (p=0.04), a lower PS volume (p=0.03) and a higher oral intake (p=0.01).

STEPS Post-hoc Study Design: Chen 2021:[1]

Post-hoc analysis of study completers of 43 patients with SBS-IF who received 0.05 mg/kg/day REVESTIVE in STEPS study and who could continue to receive REVESTIVE 0.05 mg/kg/day in STEPS-2 study. This analysis aimed to identify factors associated with sustained PN volume reduction and early vs late response among PN-dependent SBS patients treated with REVESTIVE. Outcome measures: PN volume reduction was defined as 2 consecutive visits with PN volume reduction ≥20%; time to sustained PN volume reduction was described for early and late responders. Limitations: Small sample size, and as the data are from post-hoc analysis, no final conclusions can be drawn regarding clinical outcome.[1]

Study Design: Joly 2020:[3]

A French national retrospective, multi-centre, open-label, observational cohort study of patients with SBS-IF treated with 0.05mg/kg/day REVESTIVE for at least 6 months (n=54) between Oct 2015 and March 2017. The purpose of the study was to investigate predictive factors of early response and of weaning off PS and to determine the rate of responders in a "real-life" SBS-IF cohort treated with REVESTIVE in France. Inclusion criteria are: any patient who has started treatment with REVESTIVE with follow-up of at least 6 months (54/74) to 1/09/2017. The primary outcome was the predictive factors of response and of weaning off PS 24 weeks after TED initiation. Response was defined as achievement of 20–100% reduction in daily PS volume from baseline at Week 24. Secondary outcomes were the percentage of patients who discontinued PS (weaned) and the percentage and absolute change in PS volume 24 weeks after TED initiation. Limitations: observational studies are subject to a number of confounding biases and their conclusions should be interpreted with caution.[3]

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REVESTIVE is indicated for the treatment of adult and paediatric patients 2 years of age and above with Short Bowel Syndrome (SBS) who are dependent on parenteral support. Patients should be stable for at least 4 weeks on their parenteral support regimen before initiating teduglutide therapy.[4]

References: 1. Chen K et al. Clin Nutr 2021; 43:420–427 **2.** Jeppesen PB et al. Gastroenterology 2018; 154: 874-885. **3.** Joly F et al. Clin Nutr. 2020 Sep;39 (9):2856-2862. **4.** REVESTIVE Product Information