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Summary

EFFICACY AND SAFETY OF APRAGLUTIDE ONCE-WEEKLY IN PATIENTS WITH SHORT BOWEL SYNDROME AND INTESTINAL FAILURE (SBS-IF): RESULTS FROM THE STARS STUDY – A GLOBAL PHASE 3 DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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Apraglutide, a once-weekly GLP-2 analogue, significantly reduced parenteral support volume by 25.5% versus 12.5% with placebo at 24 weeks in adults with short bowel syndrome and intestinal failure (p=0.001).

KEY POINTS

- The primary endpoint was met with a mean 13.0% greater reduction in weekly parenteral support volume at Week 24 compared to placebo, with treatment effect observed from Week 8 onward.
- A significantly higher proportion of apraglutide-treated patients achieved at least one additional day per week off parenteral support at Week 24 (43.0% vs 27.5%, p=0.040).
- In the stoma subgroup, apraglutide reduced weekly parenteral support volume by 25.6% versus 7.8% with placebo (p<0.001), while the colon-in-continuity subgroup showed a numerical but non-significant benefit (25.2% vs 17.6%, p=0.179).
- Clinical responders, defined as patients with at least 20% parenteral support reduction at both Weeks 20 and 24, were more frequent with apraglutide (42.7% vs 20.8%, p=0.003).
- Only 3.6% of apraglutide-treated patients discontinued due to an adverse event versus 1.9% with placebo, with a safety profile consistent with prior apraglutide studies in short bowel syndrome.

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