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Summary

EFFICACY ANALYSIS OF TRADIPITANT IN IDIOPATHIC AND DIABETIC GASTROPARESIS IN STUDY VP-VLY-686-3301

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Oesophagus

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A phase 3 trial of tradipitant, an NK-1 receptor antagonist, in 201 gastroparesis patients did not meet its primary endpoint of nausea reduction versus placebo but showed significant improvement on patient global impression scales.

KEY POINTS

- The primary endpoint of change in nausea severity at week 12 measured by daily diary showed similar reductions for both tradipitant (1.55) and placebo (1.49) with no statistically significant difference between groups.
- Tradipitant-treated patients showed significantly greater response on the Overall Patient Benefit scale at week 2 (81% versus 62%, p=0.0003) and week 12 (86% versus 71%, p=0.011).
- On the Patient Global Impression of Change scale, tradipitant showed significantly greater response at week 2 (74% versus 58%, p=0.019) and a trend at week 12 (78% versus 66%, p=0.065).
- The study enrolled patients with idiopathic or diabetic gastroparesis who received 85 mg tradipitant twice daily or placebo for 12 weeks, and the study was sponsored by Vanda Pharmaceuticals with author employees of the sponsor.

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