EXPOSURE-RESPONSE ANALYSIS OF OPEN LABEL TRADIPITANT IN IDIOPATHIC GASTROPARESIS IN STUDY VP-VLY-686-3301

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An exposure response analysis of the open label arm of a phase 3 trial demonstrates that idiopathic gastroparesis patients with higher tradipitant blood levels experienced significantly greater reductions in nausea severity and improvements in nausea-free days compared to those with lower drug exposure over 12 weeks.

KEY POINTS

- In 531 patients with idiopathic and diabetic gastroparesis receiving 85 mg tradipitant twice daily for 12 weeks, those with higher drug blood levels (above 140 ng/ml) had statistically greater improvement in nausea severity at Week 12 compared to the low exposure group (-1.19 vs. -0.78, $p<0.0001$).
- The high exposure subgroup achieved significantly more nausea-free days at Week 12 than the low exposure group (+35.65% vs. +22.56%, $p=0.0002$), with similar patterns observed when stratified by baseline nausea severity.
- No treatment is currently approved specifically for idiopathic gastroparesis, which affects approximately 90,000 patients in the United States and qualifies as a rare disease under FDA criteria.
- This material is relevant to clinicians treating gastroparesis and those interested in NK-1 receptor antagonist pharmacology and exposure-response relationships in gastrointestinal disorders.

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