A BASELINE SEVERITY INFLATION ANALYSIS IN STUDY VP-VLY-686-3301 OF TRADIPITANT IN GASTROPARESIS

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In a phase 3 trial, tradipitant (an NK-1 receptor antagonist) demonstrated statistically significant improvements in nausea, patient global impression of change, and overall patient benefit versus placebo in a Baseline Severity Inflation analysis subgroup of diabetic and idiopathic gastroparesis patients over 12 weeks.

KEY POINTS

- Tradipitant showed greater reduction in nausea than placebo at week 12 (-1.98 versus -1.28, p=0.028) and at week 2 (-0.99 versus -0.50, p=0.013) in the BSI subgroup.
- A higher proportion of tradipitant-treated patients demonstrated improvement on the Patient Global Impression of Change scale at week 2 (86% versus 53%, p=0.002) and week 12 (84% versus 65%, p=0.056).
- For the Overall Patient Benefit scale, more tradipitant patients showed benefit at week 2 (95% versus 68%, p=0.003) and week 12 (92% versus 68%, p=0.009).
- The BSI analysis subgroup included patients with 1 to less than 7 average vomiting episodes, excluding those with zero or highest severity vomiting, to minimize placebo effect.
- The study was sponsored by Vanda Pharmaceuticals and authors are company employees.

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