A PHASE 2B RANDOMIZED CLINICAL TRIAL OF NARONAPRIDE IN PATIENTS WITH IDIOPATHIC AND DIABETIC GASTROPARESIS

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Phase 2b trial of naronapride, a dual 5-HT4 agonist and dopamine D2 antagonist, demonstrated significant improvement in gastroparesis cardinal symptoms at 20 mg and 40 mg three times daily compared to placebo at 12 weeks.

KEY POINTS

- Naronapride 20 mg three times daily reduced the ANMS GCSI-DD Core Symptom Score versus placebo by -0.405 points (p=0.005) and 40 mg three times daily by -0.346 points (p=0.016), while 10 mg three times daily did not achieve statistical significance.
- Naronapride 20 mg and 40 mg three times daily also significantly improved disease-specific quality of life measured by PAGI-QoL total score compared to placebo (20 mg: -0.382, p=0.017; 40 mg: -0.520, p=0.001).
- The trial enrolled 328 adults (mean age 51.1 years, 79.9% female, 27.4% diabetic etiology) with idiopathic or diabetic gastroparesis and confirmed delayed gastric emptying.
- Most adverse events were dose-dependent and GI motility-related, with mild or moderate diarrhea being most common; discontinuation rates due to adverse events were 9.9% for naronapride versus 2.4% for placebo.
- There were no cardiac or prolactin-related safety signals versus placebo, and glycemic control remained stable in diabetic patients.
- Naronapride is a locally acting prokinetic with dual 5-HT4 receptor agonist and dopamine D2 receptor antagonist properties, exerting activity throughout the gastrointestinal tract.

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