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Summary

SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS OF A NOVEL LONG-ACTING GLUCAGON-LIKE PEPTIDE-2 ANALOG FT1 IN HEALTHY ADULTS

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FT1, a long-acting GLP-2 analog, demonstrated favorable safety, dose-proportional pharmacokinetics, and dose-dependent enterotrophic effects in a first-in-human phase I trial in 50 Chinese healthy adults.

KEY POINTS

- FT1 is a long-acting GLP-2 analog developed for chemotherapy-induced diarrhea prevention, with potential applications in inflammatory bowel disease, based on GLP-2's mucosal regenerative and barrier-enhancing properties.
- The randomized, double-blind, placebo-controlled phase I study (NCT06610487) evaluated single ascending doses (0.05-0.4 mg/kg) and multiple ascending doses (0.1-0.2 mg/kg once weekly for 3 weeks) administered subcutaneously.
- FT1 exhibited dose-proportional exposure with median Tmax of 24 hours, prolonged half-life of 67.6-69.1 hours, and moderate accumulation (1.42-1.73-fold) after three weekly doses.
- Plasma citrulline, a validated biomarker of enterocyte mass, showed dose- and regimen-dependent elevation; the 0.2 mg/kg weekly regimen achieved 33% greater maximal citrulline change (4,512 ng/mL) than the 0.1 mg/kg regimen and exceeded single-dose responses.
- All adverse events were Grade 1-2 with no dose-limiting toxicities or immunogenicity signals; the 0.2 mg/kg weekly regimen is supported for further evaluation in patients.

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