Abstract

Objective
This study aims to assess the efficacy and safety of Gelesis100, a novel, nonsystemic, superabsorbent hydrogel to treat overweight or obesity.

Methods
The Gelesis Loss Of Weight (GLOW) study was a 24-week, multicenter, randomized, double-blind, placebo-controlled study in patients with BMI ≥ 27 and ≤ 40 kg/m² and fasting plasma glucose ≥ 90 and ≤ 145 mg/dL. The co-primary end points were placebo-adjusted weight loss (superiority and 3% margin super-superiority) and at least 35% of patients in the Gelesis100 group achieving ≥ 5% weight loss.

Results
Gelesis100 treatment caused greater weight loss over placebo (6.4% vs. 4.4%, \( P = 0.0007 \)), achieving 2.1% superiority but not 3% super-superiority. Importantly, 59% of Gelesis100-treated patients achieved weight loss of ≥ 5%, and 27% achieved ≥ 10% versus 42% and 15% in the placebo group, respectively. Gelesis100-treated patients had twice the odds of achieving ≥ 5% and ≥ 10% weight loss versus placebo (adjusted OR: 2.0, \( P = 0.0008 \); OR: 2.1, \( P = 0.0107 \), respectively), with 5% responders having a mean weight loss of 10.2%. Patients with prediabetes or drug-naive type 2 diabetes had six times the odds of achieving ≥ 10% weight loss. Gelesis100 treatment had no apparent increased safety risks.

Conclusions
Gelesis100 is a promising new nonsystemic therapy for overweight and obesity with a highly desirable safety and tolerability profile.