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October 28, 2023

Clinical Trial Updates

Lilly and BioAge collaborate on trial of combo of tirzepatide and an apelin analog to assess weight loss while preserving lean body mass

Summary and Implications

- A Phase 2 study of the oral apelin receptor agonist BGE-105 (azelaprag) co-administered with the GLP-1/GIP receptor agonist tirzepatide for treatment of obesity will be initiated mid-2024
- The news of this collaboration comes shortly after the acquisition of Versanis in July 2023, which provided Lilly access to bimagrumab. Combined, the acquisition and partnership highlight Lilly's focus on preserving lean body mass.

Context

Clinical studies have shown that GLP-1RAs (and combination agents) lower body weight by reducing both lean body mass and fat mass (in a similar ratio to that seen in people who lose weight through diet). Lean body mass loss has been associated with an increased risk of fractures (particularly in elderly) and other adverse outcomes, although such adverse outcomes have not been observed in clinical trials of GLP-1RAs (perhaps because the trials were relatively short).

In part due to these concerns, which are to date largely theoretical, Lilly acquired Versanis in July 2023 ([link](#) to press release).

Content

BioAge is developing BGE-105 (azelaprag), which is an apelin analog. In a trial of older healthy

volunteers at bedrest, BGE-105 significantly prevented muscle atrophy and maintained muscle metabolism. In preclinical studies with diet-induced obese mice, co-administration of BGE-105 and GLP-1 doubled total weight loss compared to GLP-1 alone and normalized body composition to that of lean controls.

BioAge announced plans to initiate a Phase 2 trial of BGE-105 (azelaprag) co-administered with tirzepatide for treatment of obesity ([link](#) to press release). BioAge plans to initiate the trial in mid-2024.

The primary endpoint of the Phase 2 trial will be total weight loss, with related secondary endpoints to characterize additional potential benefits of the mechanism. BioAge will also collect aging-related biomarkers from the participants.

The collaboration is much more limited than the Versanis acquisition: Lilly will supply tirzepatide and Chorus (an operationally independent clinical development organization within Lilly) will provide clinical trial design and execution expertise. BioAge retains worldwide exclusive rights to develop and commercialize azelaprag for all indications.

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