



BioAge Labs Announces Plans for Phase 2 Trial of First-in-Class Apelin Receptor Agonist BGE-105/Azelaprag Co-Administered With Tirzepatide for Treatment of Obesity, in Collaboration With Lilly's Chorus Organization

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As part of the collaboration, Lilly will supply tirzepatide and Chorus will provide clinical trial design and execution expertise. BioAge retains worldwide exclusive rights to develop and commercialize azelaprag for all indications.

Preclinical data show that drug co-administration significantly increases total weight loss and improves body composition vs. tirzepatide alone. Phase 2 trial is planned to start in mid-2024.

RICHMOND, Calif.--([BUSINESS WIRE](#))--BioAge Labs, Inc., ("BioAge"), a clinical-stage biotechnology company developing therapeutics that target the molecular causes of aging to extend healthy human lifespan, today announced plans to initiate a Phase 2 trial of its oral apelin receptor agonist BGE-105 (azelaprag) co-administered with the GLP-1/GIP receptor agonist tirzepatide for treatment of obesity. BioAge plans to initiate the trial in mid-2024.

"Treating obesity has the potential to prevent or delay multiple diseases of aging and increase healthspan for a large segment of the population."

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Chorus ([link](#)), an operationally independent clinical development organization within Eli Lilly and Company ("Lilly") dedicated to working with biotech to develop their assets from candidate through clinical proof of concept, will advise and assist BioAge on all aspects of the Phase 2 trial design and execution, under the terms of an agreement signed by both companies. As part of the collaboration, Lilly will also provide BioAge with tirzepatide.

"We are thrilled to work directly with the clinical development experts at Chorus and benefit from Lilly's expertise in obesity drug development," said Kristen Fortney, PhD, CEO and co-founder of BioAge. "Our Phase 2 trial is designed to assess whether azelaprag can substantially increase the weight loss achieved with drugs of the incretin class. This combination could enhance the performance of both injectable and oral incretin drugs. The oral route of administration of azelaprag makes it particularly exciting as a combination partner for next-generation oral incretins currently in development. As an additional benefit, azelaprag may help promote healthier weight loss. Treating obesity has the potential to prevent or delay multiple diseases of aging and increase healthspan for a large segment of the population."

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.

In preclinical studies, co-administration of azelaprag and tirzepatide to diet-induced obese mice increased total weight loss achieved on tirzepatide alone, normalized body composition to levels observed in lean controls, and decreased fed glucose levels without an appreciable decrease in calorie intake.

Azelaprag mimics the activity of apelin, an "exerkine" peptide that is released in response to exercise. Apelin acts on skeletal muscle, heart, and central nervous system to regulate metabolism and promote muscle regeneration. Apelin signaling has demonstrated multiple benefits in energy metabolism in mouse models, including increased insulin sensitivity and reduction in fat mass.

In December 2022, BioAge announced positive topline results from a Phase 1b clinical trial showing that azelaprag treatment resulted in statistically significant prevention of muscle atrophy and maintenance of muscle protein synthesis in healthy volunteers aged 65 or older after 10 days of strict bed rest ([link](#)). Azelaprag was well tolerated in this study and at all doses tested to date in 227 subjects, with a safety profile consistent with the findings of prior phase 1 trials conducted by Amgen.

"Lilly is committed to enabling the biotech ecosystem by catalyzing breakthrough science," said Nisha Nanda, Ph.D., Group VP of External Innovation at Lilly. "We are creating access to a suite of capabilities aimed at removing barriers to innovation such as our 'one stop shop' candidate to clinical Proof of Concept development unit Chorus. We are excited about the opportunity to collaborate with BioAge to share Lilly's expertise in incretins, and utilize our Chorus clinical development engine to continue to advance the science to treat cardiometabolic diseases, like obesity."

Chorus uses an internal staff of experienced drug developers and a network of external vendors to design and implement chemistry, manufacturing and control processes, preclinical toxicology and biology, and Phase I/II clinical trials, and deliver a 'pharma-quality' data package to maximize value inflection, in a rapid and highly capital-efficient manner.

About BioAge Labs, Inc.

BioAge is a clinical-stage biotechnology company developing a pipeline of treatments to extend healthy lifespan by targeting the molecular causes of aging. The company uses its discovery platform, which combines quantitative analysis of proprietary longitudinal human samples with detailed health records to map out the key molecular pathways that impact healthy human aging. By targeting the mechanisms of aging with a large and mechanistically diverse portfolio of drugs, BioAge is unlocking opportunities to treat or even prevent age-related disease in entirely new ways. BioAge's growing portfolio includes multiple assets targeting muscle, immune, and brain aging. To date, BioAge has raised \$127M from Andreessen Horowitz, Kaiser Foundation Hospitals, and others.

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