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BioAge Announces First Patient Dosed in the STRIDES Phase 2 Clinical Trial Evaluating Azelaprag as a Novel Treatment for Obesity in Combination with Tirzepatide

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Trial to evaluate weight loss efficacy of azelaprag, an oral small molecule apelin receptor agonist that mimics key biological effects of exercise

STRIDES is being conducted in collaboration with Lilly's Chorus clinical development organization

Primary endpoint is weight loss at 24 weeks, with exploratory endpoints including body composition and physical activity

RICHMOND, Calif.--(<u>BUSINESS WIRE</u>)--BioAge Labs, Inc., ("BioAge"), a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases by targeting the biology of human aging, today announced that the first patient has been dosed in the STRIDES Phase 2 clinical trial evaluating BioAge's lead product candidate azelaprag in combination with tirzepatide for the treatment of obesity in adults aged 55 and older.

Azelaprag is an orally available small molecule agonist of the apelin receptor APJ. Apelin is an exercise-induced signaling molecule (exerkine) that acts on APJ to mediate many of the metabolic benefits of physical activity. In a Phase 1b clinical trial in healthy older volunteers on 10 days of bed rest, azelaprag was observed to improve muscle metabolism, decrease muscle atrophy, and preserve measures of resting energy expenditure and cardiorespiratory fitness (link). Azelaprag has been well tolerated in more than 240 subjects across seven Phase 1 clinical trials to date. In mouse models of obesity, the addition of azelaprag approximately doubled the weight loss achieved with incretin drugs (GLP-1 receptor agonists) while restoring healthy body composition and physical function (link).

"We believe combining azelaprag, an exercise mimetic, with tirzepatide, a GLP-1/GIP receptor agonist that decreases food intake, could provide a powerful pharmacological parallel to the exercise and diet interventions that form the foundation of obesity management," said Kristen Fortney, PhD, CEO and co-founder of BioAge. "The STRIDES trial aims to demonstrate that activating apelin signaling with azelaprag is a potent complementary mechanism that can deliver increased weight loss efficacy in patients on incretins. In addition, this trial will provide a direct read-through to azelaprag's potential as an orally available small molecule to achieve efficacy on par with injectable weight loss drugs when combined with incretins in an all-oral regimen."

STRIDES is a randomized, double-blind, placebo-controlled Phase 2 clinical trial of azelaprag in combination with tirzepatide that will enroll approximately 220 obese individuals aged 55 years and older. The trial will evaluate the efficacy, safety, and tolerability of two oral doses of azelaprag (300 mg once or twice daily) in combination with tirzepatide (5 mg subcutaneous injection once weekly). The primary endpoint is mean percent change in body weight at 24 weeks. Additional exploratory endpoints include body composition, glycemic control, obesity-related biomarkers, and patient-reported outcomes related to health and quality of life. Top-line results are anticipated in the fourth quarter of 2025.

STRIDES is being conducted in collaboration with Eli Lilly and Company's (Lilly) Chorus clinical development organization. Lilly is providing tirzepatide for the trial (link).

A second planned Phase 2 clinical trial will assess azelaprag in combination with semaglutide (Wegovy[®]) with initiation expected in the first half of 2025. Together, the trials will seek to support BioAge's therapeutic goal of developing an all-oral combination product for obesity.

About BioAge Labs

BioAge is a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. BioAge's lead product candidate, azelaprag, is an orally available small molecule agonist of APJ that was observed to promote metabolism and prevent muscle atrophy on bed rest in a Phase 1b clinical trial. In mid-2024, BioAge initiated a Phase 2 trial of azelaprag in combination with tirzepatide for the treatment of obesity in older adults. Azelaprag has potential as an oral regimen to amplify weight loss and improve body composition in patients on obesity therapy with incretin drugs. BioAge is also developing orally available small molecule brain penetrant NLRP3 inhibitors for the treatment of diseases driven by neuroinflammation. BioAge's preclinical programs, based on novel insights from the company's discovery platform built on human longevity data, also address key pathways in metabolic aging.

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