BIOAGE

BioAge Initiates Phase 2a Trial of BGE-117 in Elderly Patients with Unexplained Anemia

Multi-center, randomized, double-blind, placebo-controlled study will evaluate the efficacy and safety of BGE-117 administered daily for 12 weeks

RICHMOND, Calif., February 25, 2021 - BioAge Labs, Inc., a clinical-stage biotechnology company developing medications that target aging to treat severe diseases, today announced that it has commenced a Phase 2a clinical trial of BGE-117, an activator of hypoxia signaling, for unexplained anemia of aging (UAA). Top-line results expected in the first half of 2022.

“UAA is both highly prevalent and highly morbid, dramatically decreasing quality of life in its patients and imposing a tremendous pharmacoeconomic burden,” said Kristen Fortney, PhD, Chief Executive Officer of BioAge. “The lack of safe and effective treatments for this condition represents a major unmet clinical need.”

In this randomized, placebo-controlled, double-blind, multi-center Phase 2a trial, 160 UAA patients 65 years or older will receive daily oral doses of BGE-117 or placebo (80 patients in each group) for 3 months. The trial is being conducted in Australia, with approximately 15 sites expected to participate.

The primary endpoints of the trial are hemoglobin levels and patient-reported scores on the Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) scale, a 40-item assessment of fatigue and its impact on daily activities and function. In parallel, the study will collect data on safety and pharmacokinetic/pharmacodynamic (PK/PD) parameters. In addition, BioAge will collect data about aging biomarkers and exploratory muscle aging endpoints.

Previous clinical findings are compelling and support the Phase 2 plan. “We already know from Phase 1 trials that our drug improves EPO and Hb levels in patients who do not have UAA, and this is a primary endpoint for our Phase 2 trial,” Fortney said. “The study is therefore well suited to BioAge’s strategic approach of in-licensing de-risked clinical-stage assets.”

Following this trial, the drug also has clinical potential beyond UAA. “Because BGE-117 targets a critical pathway that is dysregulated as we age, it holds great promise for several acute and chronic conditions driven by muscle aging,” Fortney continued “Functional and biomarker data from this trial will guide our advancement of BGE-117 into additional indications, targeting multiple diseases of aging with large unmet needs, high prevalence, and huge markets.”

About Unexplained Anemia of Aging

Anemia, defined as hemoglobin of < 13.5 g/dL in men or < 12.0 g/dL in women, becomes increasingly prevalent with age, affecting 10% of people over the age of 65 and 25% of those over 85[1]. In 33% of elderly patients, anemia cannot be attributed to iron deficiency or underlying medical conditions; accordingly, these cases are classified as unexplained anemia of aging (UAA).

Patients with UAA have diminished quality of life due to fatigue, reduced mobility, and loss of independence. In addition, they are at greater risk of falling, are hospitalized more often and with longer stays, and experience overall mortality 3 to 4 times higher than non-anemic people of comparable age. The pharmacoeconomic burden is considerable: in elderly anemic patients, Medicare costs for falls alone are several billion dollars per year.

The high morbidity, prevalence, and societal cost of UAA provides a compelling rationale for developing and testing therapeutics for this condition.

About BGE-117

BGE-117, a potent, orally administered small molecule, inhibits HIF prolyl hydroxylase (HIF PH), thereby activating hypoxia-inducible factor (HIF), a key transcription factor in the cellular response to low levels of oxygen. Activation of HIF signaling improves oxygen delivery and has the potential to increase resilience, repair, and regeneration across multiple tissues and organs.

By analyzing data harvested from its proprietary biobank platform, BioAge discovered that people with higher HIF activity have higher physical and cognitive function and are significantly more likely to live to 85 or beyond, revealing a strong connection between longevity and HIF signaling. BGE-117 has the potential to treat multiple diseases of aging by boosting diverse biological processes controlled by HIF's target genes, including erythropoiesis, glycolysis, glucose uptake, vascular remodeling, and angiogenesis.

A Phase I study published by Taisho Pharmaceutical in 2018 demonstrated the clinical activity of BGE-117, showing that it increased erythropoietin (EPO) levels in patients with chronic kidney disease (CKD), and generated a safety database for 69 patients[2]. To date, HIF-PH inhibitors as a class have been shown to be well-tolerated in more than 20,000 clinical trial subjects[3].

About the BioAge Platform

The BioAge platform identifies key drug targets that impact aging. The Company's proprietary human aging cohorts include archived longitudinal blood samples collected up to 50 years ago, with participant -omics data that is tied to extensive medical follow-up records including detailed

future healthspan, lifespan, and disease outcomes. BioAge has built a systems biology and AI platform that leverages these rich datasets to generate hypotheses about the determinants of healthy human aging and identify the molecular drivers of age-related pathology. BioAge's pipeline of development candidates targeting these key pathways has the potential to address significant unmet medical needs of the aging population.

About BioAge

BioAge is a biotechnology company that develops proprietary drugs to treat aging and aging-related diseases. Since its founding in 2015, the Company has raised more than $127 million in venture capital funding from Andreessen Horowitz, Kaiser Foundation Hospitals, Khosla Ventures, Felicis Ventures, and others to back its AI-driven approach of mapping the molecular pathways that impact human longevity. BioAge's mission is to develop a pipeline of therapeutic assets that target aging to treat severe diseases.

Reference

[1]Blood. 2004;104(8):2263-2268
[2]Am J Nephrol. 2018;48(3):157-164
[3]Expert Opin Investig Drugs. 2020 Aug;29(8):831-844

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