

BIOAGE

BioAge Signs Exclusive Agreement with Amgen to Develop and Commercialize Amgen's Phase 1 APJ Agonist to Treat Diseases of Aging

BioAge's human-centric platform is a genomics-driven discovery engine for building a portfolio of drugs for aging

The platform reveals that the apelin–APJ pathway preserves muscle function in older people and predicts future longevity

BGE-105 is a well-tolerated oral agonist of APJ

RICHMOND, Calif., April 14, 2021 — BioAge Labs, Inc. a biotechnology company developing medications that target the molecular causes of aging to extend healthy human life, today announced that it has entered into an exclusive worldwide license agreement with Amgen, Inc. [Head Office: Thousand Oaks; CEO: Robert Bradway] to develop and commercialize Amgen's clinical-stage APJ agonist, BGE-105 (named AMG 986 by Amgen) to ameliorate muscle aging. In older people, muscle aging causes loss of strength, mobility, and function, driving mortality and multiple age-related diseases and decreasing overall quality of life.

APJ and its natural agonist apelin are components of a signaling pathway that regulates multiple aspects of muscle metabolism, growth, and repair.

BGE-105 is a potent APJ agonist that can be administered orally or intravenously. Phase 1 clinical trials completed in 2019 in 198 subjects who received the drug for up to 21 days showed that BGE-105 had a tolerable safety profile, with acceptable pharmacokinetics (PK) supporting once-daily administration. BioAge's first clinical trial of BGE-105, planned for initiation in the first quarter of 2022 under the existing IND, will be a Phase 1 study comparing the pharmacodynamic (PD) effects of BGE-105 in humans with those seen in previous trials examining the effects of the apelin peptide.

"BioAge's advanced proprietary platform comprehensively analyzes longitudinal human data to identify key molecular drivers of aging, which we then validate in preclinical experiments," said Kristen Fortney, PhD, BioAge's Chief Executive Officer. "Using this robust approach, we found that higher levels of apelin signalling in older people are associated with increased lifespan and reduced symptoms of frailty. Our human-first analysis suggests that the apelin-mimicking drug BGE-105 could recapitulate these positive effects in older patients."

In mice, deficiency in apelin or APJ accelerates loss of muscle function. Consistent with the key roles of apelin–APJ signaling in muscle physiology, BioAge showed in preclinical experiments that BGE-105 increases running wheel activity and other measures of frailty, improves regeneration, and decreases muscle atrophy due to immobilization in old mice.

“Maintaining muscle mass and strength is key to maintaining physical function in the elderly,” said Dr. Cedric Dray, an Associate Professor and BioAge collaborator. In 2018, Dr. Dray’s research group discovered that apelin reverses age-associated sarcopenia, and since then has collaborated with BioAge to evaluate BGE-105 in murine models of muscle regeneration. “It is tremendously exciting to trial in humans an oral APJ agonist that recapitulates the positive effects of apelin peptide.”

“As with all of BioAge’s clinical assets, BGE-105 is de-risked in two key ways,” Fortney said. “First, data from a previous clinical trial show that the molecule was well tolerated in human patients. Second, our human-centric approach reveals that the drug target is physiologically relevant to human aging — in this case, showing that enhancing apelin signaling is compatible with a long and healthy lifespan. This approach maximizes our potential for success and our ability to efficiently deliver solutions to patients for broader, more impactful outcomes.”

Under the terms of the license agreement, which covers all indications, BioAge will make an upfront payment to Amgen, who is entitled to receive development and regulatory milestone payments plus royalties based on annual net sales. Amgen will also receive BioAge shares. BioAge will be responsible for all development, manufacturing, and commercialization of BGE-105 worldwide.

“Because it targets a fundamental mechanism of muscle aging, BGE-105 could be used to treat multiple acute and chronic indications, potentially improving muscle strength in frail elderly people, shortening rehabilitation time after hip fracture, or increasing mobility after extended bed rest,” Fortney said. “The licensing agreement represents a major milestone toward our vision of developing a pipeline of treatments that separate growing older from disability and disease, dramatically improving the quality of life as we age.”

About BioAge

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 tracking individuals over the lifespan, to map out the key molecular pathways that impact healthy human aging, thus revealing the causes of age-related disease. By targeting the mechanisms of aging with a large and mechanistically diverse portfolio of drugs, BioAge will unlock opportunities to treat or even prevent these diseases in entirely new ways. To date, BioAge has raised \$127M from Andreessen Horowitz, Kaiser Foundation Hospitals, and others. In early 2021, BioAge initiated Phase 2 clinical trials

of two in-licensed drugs: BGE-117, a potent inhibitor of HIF PH, is being tested for unexplained anemia of aging, and will be developed for indications related to muscle weakness; BGE-175, a PGD2 DP1 receptor inhibitor, is being tested for COVID-19, and will be developed for disorders of the aging immune system. For additional information about BioAge, visit the company's website at www.bioagelabs.com.

Source: BioAge Labs, Inc.

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