BioAge Announces Positive Interim Phase 1 Data for BGE-102, a Novel Brain-Penetrant NLRP3 Inhibitor

December 4, 2025

BGE-102 was well-tolerated in SAD and initial MAD cohorts, with a pharmacokinetic profile supporting once-daily oral dosing

Strong target engagement: BGE-102 achieved 90-98% suppression of IL-1β, a cytokine directly downstream of NLRP3, at Day 14

High brain penetration: BGE-102 doses of 60 mg and higher exceeded target IC90 levels in cerebrospinal fluid (CSF) at Day 14

Company is expanding the Phase 1 trial to include MAD cohorts in participants with obesity and elevated hsCRP, with data anticipated in first half of 2026

EMERYVILLE, Calif., Dec. 04, 2025 (GLOBE NEWSWIRE) -- BioAge Labs, Inc. (Nasdaq: BIOA) ("BioAge"), a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases by targeting the biology of human aging, today announced positive interim data from the ongoing Phase 1 single ascending dose (SAD) / multiple ascending dose (MAD) clinical trial evaluating BGE-102, a potent, structurally novel, orally available, brain-penetrant small molecule NLRP3 inhibitor being developed for treatment of patients with cardiovascular risk factors.

“We’re very encouraged by the interim data from our ongoing Phase 1 trial of BGE-102, an NLRP3 inhibitor with best-in-class potential. Once-daily doses of 60 mg and above were well tolerated and exceeded target IC90 levels in both the periphery and the brain,” said Kristen Fortney, PhD, CEO and co-founder of BioAge. “The clear evidence of high brain penetration is especially important, as it supports BGE-102’s potential to comprehensively target NLRP3-driven inflammation in both the central nervous system and peripheral tissues.”

Key Initial Findings from the Phase 1 Study

Safety & Tolerability

- BGE-102 treatment was well tolerated across all dose levels evaluated to date in SAD (10, 30, 60, and 120 mg) and MAD (60 and 120 mg) cohorts
- Adverse events were infrequent and mild to moderate in severity, and all resolved without intervention; full analysis to follow after database lock and unblinding in the first half of 2026

Pharmacokinetics & Pharmacodynamics

- Dose proportionality observed across doses tested
- BGE-102 treatment achieved 90% (60 mg dose) to 98% (120 mg dose) suppression of IL-1β production in an ex vivo whole blood stimulation assay prior to dosing on Day 14
- In MAD cohorts, treatment with BGE-102 at 60 mg and higher achieved plasma concentrations exceeding IC90 for 24 hours

CNS Penetration

- In MAD cohorts, BGE-102 doses of 60 mg and higher resulted in CSF concentrations exceeding the IC90 after 14 days
- High brain penetration is a key differentiator from other NLRP3 inhibitors in development, enabling the targeting of both peripheral and central inflammation

Phase 1 Study Design

The ongoing Phase 1 study is a randomized, double-blind, placebo-controlled trial in healthy volunteers and obese participants. Part 1 evaluated SAD at four dose levels (10, 30, 60, and 120 mg); Part 2 evaluated MAD administered once daily for 14 days in healthy volunteers (60 mg and 120 mg). Pharmacodynamic effects were evaluated using an *ex vivo* whole blood stimulation assay that measures BGE-102's ability to inhibit production of the key inflammatory signal IL-1β, which is directly downstream of NLRP3.

Part 2 has been expanded to evaluate two dose levels in obese participants with elevated hsCRP. The MAD portion in obese participants is ongoing, with data anticipated in the first half of 2026.

"Recent clinical experience has shown that NLRP3 inhibitors can achieve substantial reductions in inflammatory biomarkers such as hsCRP within the first week of treatment," said Paul Rubin, MD, Chief Medical Officer of BioAge. "Because IL-1β is a key upstream regulator of CRP production, the potent and sustained IL-1β suppression we observed with BGE-102 has the potential to translate directly into meaningful effects on hsCRP. As a result, we have expanded the current trial with additional cohorts of obese participants with elevated baseline inflammation with the goal of providing early potential biomarker proof-of-concept."

Figures and data from the ongoing Phase 1 study are available in the Company's corporate presentation at https://ir.bioagelabs.com/.

Anticipated Milestones

- **1H26:** Completion of Phase 1 MAD cohorts in obese participants with elevated hsCRP, evaluating changes in key inflammatory biomarkers including hsCRP and IL-1β
- **1H26**: Initiation of Phase 2a proof-of-concept study in patients with obesity and cardiovascular risk factors.
    - The trial is planned to enroll approximately 100 patients randomized 1:1 to placebo or BGE-102 monotherapy for 12 weeks. The anticipated primary endpoint of the trial is percent change in hsCRP. Additionally, the trial will assess a range of inflammatory and metabolic biomarkers, and will include MRI imaging.
- **2H26**: Phase 2a data readout

Background on BGE-102 and NLRP3

BGE-102 is a potent, orally available, brain-penetrant small molecule NLRP3 inhibitor being developed for cardiovascular risk factors in patients with obesity. BGE-102 represents a structurally novel class of NLRP3 inhibitors developed by BioAge with a unique mechanism and binding site. NLRP3 is a key driver of age-related inflammation that has been implicated in a broad range of diseases, including cardiovascular disease, neurodegenerative conditions, and metabolic disorders. NLRP3 inhibition is a promising emerging strategy for reducing levels of inflammatory biomarkers associated with cardiovascular risk.

About BioAge Labs, Inc.

BioAge is a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases by targeting the biology of human aging. The Company's lead product candidate, BGE-102, is a potent, orally available, brain-penetrant small-molecule NLRP3 inhibitor being developed for obesity and cardiovascular risk factors. A Phase 1 SAD/MAD trial of BGE-102 is underway, with topline data including additional MAD cohorts anticipated by 1H26. The Company is also developing long-acting injectable and oral small molecule APJ agonists for obesity. BioAge's additional preclinical programs, which leverage insights from the Company's proprietary discovery platform built on human longevity data, address key pathways involved in metabolic aging.

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our plans to develop and commercialize our product candidates, including BGE-102 and our APJ program, the potential for BGE-102 as a treatment for cardiovascular risk and the expected timeline for future data readouts from our ongoing Phase 1 clinical trial, the timing and results of our clinical trials, risks associated with clinical trials, including our ability to adequately manage clinical activities, the timing of our IND filing for our APJ program, the timing of and our ability to obtain and maintain regulatory approvals and the clinical utility of our product candidates. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "potential," "possible," "will," "would," and other words and terms of similar meaning. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our ability to develop, obtain regulatory approval for and commercialize our product candidates; the timing and results of preclinical studies and clinical trials; the risk that positive interim results in a preclinical study or clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events; failure to protect and enforce our intellectual property, and other proprietary rights; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; risks relating to technology failures or breaches; our dependence on collaborators and other third parties for the development of product candidates and other aspects of our business, which are outside of our full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions, including due to the imposition of tariffs and other trade barriers; risks associated with current and potential future healthcare reforms; risks relating to attracting and retaining key personnel; changes in or failure to comply with legal and regulatory requirements, including shifting priorities within the U.S. Food and Drug Administration; risks relating to access to capital and credit markets; and the other risks and uncertainties that are detailed under the heading "Risk Factors" included in BioAge's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on November 6, 2025, and BioAge's other filings with the SEC filed from time to time. BioAge undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Contacts

PR: Chris Patil, media@bioagelabs.com
IR: Dov Goldstein, ir@bioagelabs.com
Partnering: Peng Leong, partnering@bioagelabs.com
Web: https://bioagelabs.com