BioAge Labs Announces First Participant Dosed in QUELL-CV, a Phase 2 Proof-of-Concept Trial of BGE-102, a Novel Oral NLRP3 Inhibitor, in Patients at Elevated Cardiovascular Risk

June 16, 2026

Randomized, double-blind, placebo-controlled, dose-ranging trial evaluating three once-daily oral doses of BGE-102 in participants with elevated systemic inflammation and additional cardiovascular risk factors

Primary endpoint is percent change in high-sensitivity C-reactive protein (hsCRP); trial designed to support optimal dose selection for Phase 3

Trial builds on previously reported Phase 1 results in which BGE-102 achieved potential best-in-class hsCRP reductions and was well tolerated across all dose levels

Topline data anticipated in the second half of 2026

EMERYVILLE, Calif., June 16, 2026 (GLOBE NEWSWIRE) -- BioAge Labs, Inc. (Nasdaq: BIOA) ("BioAge" or the "Company"), a clinical-stage biopharmaceutical company developing therapeutic product candidates for cardiometabolic diseases by targeting the biology of human aging, today announced that the first participant has been dosed in QUELL-CV, a Phase 2 proof-of-concept clinical trial of BGE-102, a potent, structurally novel, orally available, brain-penetrant small molecule NLRP3 inhibitor. BGE-102 is being developed as a once-daily oral therapy, with cardiovascular risk reduction as the lead indication.

"Inflammation is increasingly recognized as a major modifiable driver of cardiovascular events, on par with elevated LDL cholesterol — and an oral therapy that addresses it could transform care and outcomes the way statins did decades ago," said Kristen Fortney, Ph.D., CEO and co-founder of BioAge. "Our recently reported Phase 1 results positioned BGE-102 as a potential best-in-class NLRP3 inhibitor, with profound hsCRP reductions on a well-tolerated, once-daily oral dose. QUELL-CV will inform optimal dose selection in Phase 3 and BGE-102's path forward in cardiovascular disease. With a second proof-of-concept study in diabetic macular edema planned to start mid-2026, we are positioned to demonstrate BGE-102's broad potential."

QUELL-CV Trial Design

QUELL-CV is a randomized, double-blind, placebo-controlled, dose-ranging Phase 2 proof-of-concept trial evaluating BGE-102 in participants at elevated cardiovascular risk.

- **Population:** Approximately 160 adults with obesity, elevated systemic inflammation (hsCRP >3 mg/L), and at least one additional cardiovascular risk factor
- **Arms (n = 40 each):** Placebo, BGE-102 30 mg QD, BGE-102 60 mg QD, BGE-102 90 mg QD (all oral)
- **Duration:** 12 weeks of once-daily dosing
- **Primary endpoint:** Percent change from baseline in hsCRP
- **Additional endpoints include:** Proportion of participants achieving hsCRP normalization (<2 mg/L), and additional inflammatory, cardiometabolic, and imaging biomarkers

Topline data are anticipated in the second half of 2026.

"hsCRP is among the most predictive biomarkers of cardiovascular risk, and the link between inflammation and atherothrombotic events is now clinically actionable," said Paul Rubin, M.D., Chief Medical Officer of BioAge. "QUELL-CV is designed to characterize the dose-response relationship of BGE-102's effect on hsCRP across three oral once-daily dose levels in participants with obesity, elevated systemic inflammation, and additional cardiovascular risk factors, and to assess its effects on an expanded set of inflammatory and metabolic biomarkers."

About BGE-102 and NLRP3

BGE-102 is a potent, structurally novel, orally available, brain-penetrant small molecule NLRP3 inhibitor discovered by BioAge. NLRP3 is a central driver of age-related chronic inflammation that has been implicated in cardiovascular disease, metabolic disorders including obesity, and neurodegenerative conditions. NLRP3 activation has also been identified as a central feature of multiple inflammation-driven retinal diseases, including diabetic macular edema and geographic atrophy. BioAge's discovery platform identified NLRP3 as a therapeutic target based on analysis of human aging cohorts, which revealed that reduced NLRP3 activity is associated with greater longevity.

In a Phase 1 SAD/MAD trial in healthy volunteers and participants with obesity and elevated systemic inflammation, BGE-102 achieved median hsCRP reductions of 86% at both 60 mg and 120 mg once-daily oral doses, with 87–93% of participants on active treatment achieving normalized hsCRP (<2 mg/L). Additional inflammatory and cardiovascular risk biomarkers, including IL-6 and fibrinogen, were also reduced in these participants. BGE-102 demonstrated pharmacokinetics consistent with once-daily oral dosing, CSF exposure at or above its IC90 for IL-1β inhibition, and ≥90% suppression of IL-1β at trough in an ex vivo whole-blood assay. BGE-102 was well tolerated across all dose levels evaluated, with no serious adverse events, no treatment-emergent adverse events leading to discontinuation, and no clinically meaningful changes in vital signs, ECGs, or laboratory values.

BioAge also plans to initiate a Phase 1b/2a proof-of-concept trial of BGE-102 in patients with diabetic macular edema (DME) in mid-2026, with results anticipated in mid-2027, building on BioAge's prior announcement of the ophthalmology expansion of the BGE-102 program.

About BioAge Labs, Inc.

BioAge is a clinical-stage biopharmaceutical company developing therapeutic product candidates for cardiometabolic diseases by targeting the biology of human aging. The Company's lead product candidate, BGE-102, is a potent, structurally novel, orally available, brain-penetrant small-molecule NLRP3 inhibitor being developed for cardiovascular risk and retinal diseases including diabetic macular edema. BGE-102 has completed a Phase 1 SAD/MAD trial demonstrating a well-tolerated profile and potential best-in-class reductions in hsCRP and other inflammatory biomarkers in participants with obesity and elevated inflammation. Phase 2 cardiovascular risk proof-of-concept data are anticipated by end of year 2026, and Phase 1b/2a diabetic macular edema proof-of-concept data are anticipated in mid-2027. 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. In some cases, you can identify forward-looking statements by terms such as "aim," "may," "will," "should," "expect," "forecast," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this press release, including without limitation statements regarding our plans to develop and commercialize our product candidates, including BGE-102 and our APJ programs, the potential for BGE-102 as a treatment for atherosclerotic cardiovascular disease risk reduction and diabetic macular edema, the expected timeline for data readouts from our ongoing Phase 2 clinical trial, the expected timing and results of our ongoing or planned preclinical studies and clinical trials, risks associated with clinical trials, including our ability to adequately manage clinical activities for BGE-102 and our APJ programs, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, the timing of and our ability to obtain and maintain regulatory approvals, the clinical utility of our future product candidates, our commercialization, marketing and manufacturing capabilities and strategy, our expectations about the willingness of healthcare professionals to use our product candidates, the sufficiency of our cash, cash equivalents and marketable securities, general economic conditions, the impact of industry and market conditions on our operations, including fluctuating interest rates and inflation, increased volatility in the debt and equity markets, legislative or regulatory healthcare reforms in the United States, significant political, trade or regulatory developments, including tariffs, federal government shutdowns, or shifting priorities within the U.S. Food and Drug Administration, cybersecurity incidents, and global regional conflicts, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this press release are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in BioAge's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on May 8, 2026, and BioAge's other filings with the SEC filed from time to time.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. 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
Website: https://bioagelabs.com