BioAge Labs Announces First Participant Dosed in QUELL-DME, a Phase 2 Trial of BGE-102, a Novel Oral NLRP3 Inhibitor, in Diabetic Macular Edema

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Randomized, controlled, approximately 180-participant trial evaluates oral BGE-102 as monotherapy and in combination with anti-VEGF therapy

Primary endpoint is change in best-corrected visual acuity at week 12

Topline results expected in the second half of 2027

Beyond DME, results will inform development strategy in other NLRP3-driven retinal diseases, including geographic atrophy

EMERYVILLE, Calif., Sept. 08, 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-DME, a randomized, controlled Phase 2 trial evaluating once-daily oral BGE-102 in adults with diabetic macular edema (DME). The approximately 180-participant study will evaluate BGE-102 both as monotherapy and in combination with standard-of-care anti-VEGF therapy, with change in best-corrected visual acuity at week 12 as the primary endpoint. BGE-102 is a structurally novel, once-daily oral NLRP3 inhibitor.

"NLRP3 is a compelling target in DME because it sits upstream of the inflammation that drives vascular leakage and vision loss. The disease affects about one million people in the United States and is a leading cause of vision loss in working-age adults. Standard care still requires repeated injections into the eye; many patients delay starting treatment, miss doses, or never achieve adequate disease control," said Kristen Fortney, Ph.D., CEO and co-founder of BioAge. "QUELL-DME asks a straightforward question: can once-daily oral BGE-102 improve vision? Dosing the first participant marks an important milestone for the program. The trial's results will also guide development in other NLRP3-driven retinal diseases, including geographic atrophy."

"NLRP3 sits upstream of key disease processes implicated in DME, including IL-1β and IL-18 release, pyroptosis, VEGF production, and disruption of the blood-retinal barrier," said Paul Rubin, M.D., Chief Medical Officer of BioAge. "Prior interventional studies of intravitreal IL-6 inhibition provide clinical support for inflammation as a therapeutic target in macular edema. QUELL-DME's three-arm design lets us evaluate the two potential roles for oral BGE-102 in DME: as monotherapy and as an add-on to anti-VEGF treatment. Because DME develops in the setting of diabetes, systemic NLRP3 inhibition may benefit the eye by acting on both local retinal inflammation and the broader inflammatory state that contributes to the disease."

QUELL-DME Trial Design

QUELL-DME is a randomized, controlled, three-arm Phase 2 trial evaluating oral BGE-102 in patients with diabetic macular edema, both as monotherapy and as an add-on to standard-of-care anti-VEGF intravitreal therapy.

- **Population:** Approximately 180 adults with diabetic macular edema, randomized 1:1:1
- **Arms:** Intravitreal anti-VEGF + oral placebo, intravitreal anti-VEGF + BGE-102 90 mg QD, sham (simulated) intravitreal injection + BGE-102 90 mg QD
- **Duration:** 12 weeks of once-daily oral dosing, with 4-week follow-up
- **Primary endpoint:** Change from baseline in best-corrected visual acuity (BCVA) at week 12
- **Exploratory endpoints:** Measures of retinal parameters and intraocular and plasma biomarkers

Topline results are anticipated in the second half of 2027.

About BGE-102 and NLRP3

BGE-102 is a structurally novel, potent, 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.

BioAge is also conducting QUELL-CV, a Phase 2 dose-ranging trial evaluating BGE-102 in patients with obesity and elevated baseline inflammation; QUELL-CV has completed enrollment, and topline data are anticipated in the second half of 2026. In a Phase 1 SAD/MAD trial in healthy volunteers and participants with obesity and elevated systemic inflammation, BGE-102 demonstrated potential best-in-class reductions in hsCRP and other inflammatory biomarkers.

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, orally bioavailable, brain-penetrant small-molecule NLRP3 inhibitor being developed for diseases driven by inflammation, including diabetic macular edema and cardiovascular risk. 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.

Phase 2 cardiovascular proof-of-concept data from QUELL-CV are anticipated in the second half of 2026, and Phase 2 diabetic macular edema data from QUELL-DME are anticipated in the second half of 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 diabetic macular edema, the expected timeline for data readouts from our ongoing Phase 2 clinical trials, 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 August 5, 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: partnering@bioagelabs.com
Website: https://bioagelabs.com