NGM Announces Completion of Enrollment in Phase 2 CATALINA Study of NGM621 in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

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- Geographic atrophy is a progressive, irreversible retinal degenerative disease that can lead to blindness, with no currently approved treatments
- NGM621 is a monoclonal antibody against complement C3, a protein implicated in the pathophysiology of geographic atrophy, and is engineered with the goal of potently inhibiting the central component of the complement cascade by blocking all of its initiating pathways to reduce disease progression
- Multicenter, randomized, double-masked, sham-controlled study enrolled 320 patients
- NGM anticipates Phase 2 CATALINA study topline data readout in the second half of 2022

SOUTH SAN FRANCISCO, Calif., July 22, 2021 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced it has completed enrollment in the Phase 2 CATALINA study, which is evaluating the safety and efficacy of intravitreal (IVT) injections of NGM621 in patients with geographic atrophy secondary to age-related macular degeneration. Geographic atrophy is characterized by progressive retinal cell loss that results in irreversible loss of vision, and the disease affects approximately 1 million patients in the U.S. and 5 million patients globally. There are no approved treatments for geographic atrophy.

“Patients living with geographic atrophy, like those enrolled in CATALINA, may face significant and progressive vision loss that has far-reaching implications, including a loss of independence, depression and an increased risk of falls and fractures. Completing enrollment in CATALINA is an important milestone for NGM and the patients with geographic atrophy that we hope to serve. NGM621, as a monoclonal antibody with a high potency targeting C3 and the potential for every-eight-week dosing, may offer an innovative treatment option for this underserved patient population,” said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM. “We are highly encouraged by the program’s progress to date and for the potential of NGM621 to change the disease trajectory for geographic atrophy patients.”

The Phase 2 CATALINA study enrolled a total of 320 patients with geographic atrophy, more than the originally planned 240 patients. Patients were enrolled and randomized to receive IVT injections of NGM621 or sham every four or eight weeks. The primary efficacy endpoint is the rate of change in geographic atrophy lesion area, as measured by fundus autofluorescence (FAF) imaging, over 52 weeks of treatment. NGM621 Phase 1 study results, which were first presented at the American Academy of Ophthalmology in November 2020, supported the advancement of the drug to the ongoing Phase 2 study.

“Building upon encouraging Phase 1 results demonstrating that NGM621 was well-tolerated and had an acceptable safety profile, the CATALINA study will provide additional safety information and will inform whether NGM621 may slow disease progression in patients with geographic atrophy,” said Arshad M. Khanani, M.D., M.A., Managing Partner, Director of Clinical Research, and Director of Fellowship at Sierra Eye Associates and Clinical Associate Professor at the University of Nevada, Reno School of Medicine. “Complement inhibition continues to be a promising approach for the treatment of geographic atrophy, a disease that represents a major unmet need in ophthalmology, affecting millions of people around the world. As a retina specialist, it is extremely difficult to watch my geographic atrophy patients’ disease worsen without being able to intervene effectively. I look forward to seeing top-line results from the CATALINA study next year, as we continue to strive for meaningful medical advancements for these patients.”

About NGM621 and Complement C3 Inhibition

NGM621 is a humanized IgG1 monoclonal antibody engineered to potently inhibit complement C3. The therapeutic is delivered via intravitreal (IVT) injection and is being evaluated with dosing intervals of every four and eight weeks. NGM621 Phase 1 study results showed single and multiple IVT injections appeared to be safe and well tolerated (clinicaltrials.gov identifier: NCT04014777). In preclinical models, NGM621’s high affinity binding to C3 has demonstrated the potential for potent C3 inhibition, and NGM’s pharmacokinetics/pharmacodynamics modeling has shown sufficient drug coverage for potential every-eight-week dosing. The company’s preclinical data also suggest that NGM621, unlike PEGylated molecules, may not exacerbate choroidal neovascularization (CNV); the human translation of this observation is being investigated in the Phase 2 CATALINA clinical trial.

C3 is a key component of the complement system, which helps orchestrate the body’s response to infection and maintains tissue homeostasis. The complement cascade can be activated through its three distinct pathways – classical, lectin and alternative – all of which converge to activate C3. When this cascade is dysregulated, the immune response may lead to the development and progression of geographic atrophy. Inhibition of C3 represents a promising therapeutic approach that broadly inhibits downstream effector functions triggered by the excessive activation of C3, including inflammation, activation of the adaptive immune system, opsonization (the marking of a pathogen to be destroyed by phagocytes, a type of immune cell), phagocytosis and cell lysis (cell death).

NGM621 was discovered by NGM under its strategic collaboration with Merck.

About the NGM621 Phase 2 CATALINA Study

The Phase 2 CATALINA study enrolled 320 patients diagnosed with geographic atrophy in one or both eyes. The primary objectives of this multicenter, randomized, double-masked, sham-controlled study are to evaluate the efficacy and safety of NGM621 IVT injections compared to sham control. Patients will be randomized to one of four treatment groups to receive IVT injections of NGM621 or sham every four- or eight-weeks for a total of 52 weeks, and monitored for an additional four weeks upon treatment completion. The primary efficacy endpoint is the rate of change in geographic atrophy lesion area, as measured by fundus autofluorescence (FAF) imaging, over 52 weeks of treatment. The primary safety endpoints will evaluate the incidence and severity of ocular and systemic adverse events from treatment with NGM621 compared to sham control.

For more information, please visit the study listing on clinicaltrials.gov (identifier: NCT04465955).

About NGM Biopharmaceuticals, Inc.

NGM is a biopharmaceutical company focused on discovering and developing novel therapeutics based on scientific understanding of key biological pathways underlying retinal diseases, cancer, and liver and metabolic diseases. We leverage our biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that enable us to move rapidly into proof-of-concept studies and deliver potential first-in-class medicines to patients. At NGM, we aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. All of our therapeutics have been generated by our in-house discovery engine; today, we have six disclosed programs, including four in Phase 2 or 2b studies, across three therapeutics areas. Visit us at www.ngmbio.com for more information.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “with the goal of,” “engineered to,” “anticipates,” “may,” “suggest,” “potential,” “will,” “look forward,” “aspire” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to: NGM’s strategy to deliver transformative medicines for patients across a range of therapeutic areas through the clinical development of NGM621 and other product candidates; the design, timing and potential results of NGM’s Phase 2 CATALINA study of NGM621; the availability of Phase 2 CATALINA study topline data readout in the second half of 2022; the ability of NGM621 to serve as an innovative treatment option for patients with geographic atrophy; the potential for every-eight-week dosing of NGM621 and the suggestion that NGM621 may not exacerbate CNV; the potential of NGM621 to change disease trajectory and slow disease progression for geographic atrophy patients; the potential therapeutic effects, benefits and dosing schedule of NGM621 and the role of NGM621 as a potential potent C3 inhibitor engineered with the goal of inhibiting the central component of the complement cascade by blocking all of its initiating pathways and that may have the effect of reducing disease progression in patients with geographic atrophy; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM’s current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM could differ materially from those described in or implied by the forward-looking statements in this press release. These risks and uncertainties include, without limitation, risks and uncertainties associated with: the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in receiving regulatory clearance and the risk that CATALINA study and future studies in humans may show that NGM621 is not a safe and effective treatment for patients with geographic atrophy; the risk that the results obtained to date in NGM’s clinical trials may not be indicative of results obtained in pivotal or other late-stage trials; the evolving effects of the COVID-19 pandemic, which may significantly impact (i) our business and operations, including activities at our headquarters in the San Francisco Bay Area and our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital and (iii) the value of our common stock; the time-consuming and uncertain regulatory approval process; NGM’s reliance on third-party manufacturers for NGM621 and its other product candidates; the sufficiency of NGM’s cash resources and need for additional capital; and other risks and uncertainties affecting NGM and its development programs, including those described under the caption “Risk Factors” in NGM’s quarterly report on Form 10-Q for the quarter ended March 31, 2021 and future filings and reports that NGM makes from time to time with the United States Securities and Exchange Commission. Except as required by law, NGM assumes no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

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