NGM Bio's NGM621 Receives Fast Track Designation from the FDA for the Treatment of Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

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SOUTH SAN FRANCISCO, Calif., Feb. 07, 2022 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to NGM621, a monoclonal antibody product candidate engineered to potently inhibit complement C3, for the treatment of patients with geographic atrophy (GA) secondary to age-related macular degeneration. NGM Bio is currently evaluating NGM621 in its ongoing Phase 2 CATALINA study and a topline data readout is expected in the fourth quarter of 2022.

"The FDA's decision to grant Fast Track designation to NGM621 is an important milestone underscoring the high unmet medical need for patients with geographic atrophy as well as the potential of NGM621 to alter the course of this disease for those underserved patients," stated Erin Henry Ph.D., Head of Ophthalmology at NGM Bio. "Patients living with geographic atrophy lose approximately one line of vision on the eye chart each year, impacting their ability to do everyday tasks such as driving and reading and reducing their independence and quality of life. We are committed to improving outcomes for these patients and this designation, with its potential for more frequent interactions with the FDA, may help accelerate our efforts to do so."

The Fast Track process was designed by the FDA to facilitate the development and expedite the review of potential therapeutics intended to treat serious conditions and address unmet medical needs. Fast Track-designated programs are given the opportunity to engage in early and frequent communication with the FDA throughout the entire development and review process and may be eligible for prioritized review and accelerated approval if relevant criteria are met.

About Geographic Atrophy (GA)

GA is an advanced form of age-related macular degeneration characterized by progressive retinal cell loss that results in irreversible loss of vision. The disease affects approximately one million patients in the U.S. and five million patients globally. There are currently no treatments for GA approved by the FDA or the European Medicines Agency.

About NGM621 and Complement C3 Inhibition

NGM621 is a proprietary humanized Immunoglobulin 1 monoclonal antibody product candidate engineered to potently bind to, and be a long-acting inhibitor of, complement C3 activity. 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 Bio's pharmacokinetics/pharmacodynamics modeling has shown sufficient drug coverage for potential every-eight-week dosing. NGM Bio'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 fully enrolled, ongoing Phase 2 CATALINA clinical trial (clinicaltrials.gov identifier: NCT04465955).

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 GA. Inhibition of C3 represents a promising therapeutic approach that broadly inhibits downstream effector functions triggered by the excessive activation of the complement pathway, 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 Bio under its strategic collaboration with Merck, known as MSD outside the United States and Canada.

About the NGM621 Phase 2 CATALINA Study

The Phase 2 CATALINA study enrolled 320 patients diagnosed with GA 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 when given every four weeks or every eight weeks via IVT injections compared to sham control. Patients are randomized to one of four treatment groups in a ratio of 2:1:2:1 to receive IVT injections of NGM621 or sham every four weeks or every eight weeks for a total of 52 weeks and monitored for an additional four weeks upon treatment completion for a total of 56 weeks. The primary efficacy endpoint is the rate of change in GA 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 Bio is focused on discovering and developing novel, life-changing medicines for people whose health and lives have been disrupted by disease. The company's biology-centric drug discovery approach aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement

into proof-of-concept studies. As explorers on the frontier of life-changing science, NGM Bio aspires to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in the NGM Bio pipeline have been generated by its in-house discovery engine, with a disease-agnostic mindset, always led by biology and motivated by unmet patient need. Today, the company has seven disclosed programs, including four in Phase 2 or 2b studies, across three therapeutic areas: cancer, retinal diseases and liver and metabolic diseases. 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 Bio'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 potential for early and more frequent interactions with the FDA; the design, timing and potential results of NGM Bio's Phase 2 CATALINA study of NGM621; the availability of Phase 2 CATALINA study topline data readout in the fourth quarter of 2022; the ability of NGM621 to serve as an innovative treatment option for patients with GA; 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 GA 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 GA; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM Bio's current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM Bio 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 GA; the risk that the results obtained to date in NGM Bio'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 Bio's reliance on third-party manufacturers for NGM621 and its other product candidates; the sufficiency of NGM Bio's cash resources and need for additional capital; and other risks and uncertainties affecting NGM Bio and its development programs, including those described under the caption "Risk Factors" in NGM Bio's quarterly report on Form 10-Q for the quarter ended September 30, 2021 filed with the United States Securities and Exchange Commission (SEC) on November 4, 2021 and future filings and reports that NGM Bio makes from time to time with the SEC. Except as required by law, NGM Bio 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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