NGM Bio Announces Initiation of Phase 2 CATALINA Study of NGM621 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

July 27, 2020

-- Multicenter, randomized, double-masked, sham-controlled study will evaluate safety and efficacy of intravitreal injections of NGM621 every four or eight weeks for 48 weeks --

-- GA is a progressive, irreversible retinal degenerative disease with no approved therapies --

-- NGM621, a monoclonal antibody, is engineered to potently inhibit complement C3 with the treatment goal of reducing disease progression in patients with GA --

SOUTH SAN FRANCISCO, Calif., July 27, 2020 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced it has initiated the Phase 2 CATALINA study, a multicenter, randomized, double-masked, sham-controlled clinical trial, to evaluate the safety and efficacy of intravitreal injections (IVT) of NGM621 in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). GA, an advanced form of AMD, is a progressive retinal degenerative disease associated with irreversible loss of vision, diminished quality of life and eventual blindness. Dysregulated activation of the complement system, a key component of the immune system, has been implicated in the onset and progression of GA. NGM621 is a humanized IgG1 monoclonal antibody engineered to potently inhibit activity of complement C3 with the treatment goal of reducing disease progression in patients with GA, and with the potential for every eight week dosing.

“The NGM621 program exemplifies our strategy to target powerful, disease-driving biology to deliver transformative medicines for patients across a range of therapeutic areas and diseases with high unmet need,” Hsiao D. Lieu, M.D., Chief Medical Officer at NGM Bio. “We are very encouraged by the preclinical data and Phase 1 safety and tolerability data for NGM621. Recognizing the severe, life-altering impact GA has on patients’ lives, we are working to rapidly advance NGM621 through clinical development. We believe NGM621 offers a unique profile with best-in-class potential and could represent an important therapeutic advance for patients with GA.”

NGM621 was discovered by NGM under its strategic collaboration with Merck. NGM successfully completed a first-in-human open-label Phase 1 study in which treatment with single- and multiple-dose IVT injections of NGM621 in patients with GA was well tolerated, supporting continued development. NGM plans to present the data from the Phase 1 study at an upcoming medical conference. NGM recently presented NGM621 preclinical findings at The Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, held virtually in June 2020. The presentations are available on NGM’s website here.

“As a retina specialist who manages patients with GA, I see first-hand the progressive and eventually devastating impact this disease can have on patients’ quality of life. The insidious loss of vision leads to difficulty with everyday tasks and social isolation, in many cases robbing patients of their independence and ability to do things they enjoy. Often these patients live in fear of going blind, knowing that currently nothing can be done to slow their disease progression,” said Charles C. Wykoff, M.D., Ph.D., Director of Research at Retina Consultants Houston and the Greater Houston Retina Research Foundation. “Complement inhibition continues to be a promising approach to slowing GA progression. I am pleased to see NGM621 move into a rigorous Phase 2 study and am encouraged by the data to date with this antibody that blocks C3 activation. I look forward to seeing how NGM621’s C3 inhibition translates into clinical benefit.”

About the NGM621 Phase 2 CATALINA Study Design

Designed as a Phase 3-enabling study, the Phase 2 CATALINA study will enroll 240 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 IVT injections compared to sham control. Patients will be 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 48 weeks, and monitored for an additional four weeks upon treatment completion. The primary efficacy endpoint is change from baseline in the square root of GA lesion area at 48 weeks, as measured by fundus autofluorescence (FAF) imaging compared to sham control. 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.

About NGM621 and Complement C3 Inhibition

NGM621 is a humanized IgG1 monoclonal antibody engineered to potently inhibit complement C3, with the potential for extended every eight week dosing without pegylation. In preclinical models, NGM621’s high affinity binding to C3 has demonstrated the potential for potent C3 inhibition. In addition, in well validated animal models of laser-induced choroidal neovascularization (CNV), C3 inhibition has demonstrated the ability to reduce retinal vascular leakage, suggesting the potential for NGM621 to prevent CNV development.

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 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).

About AMD and GA

AMD is a leading cause of vision loss and blindness in people over the age of 65 in the US and other industrialized countries.[i] The two advanced stages of the disease are called neovascular (wet) AMD and geographic atrophy.

GA is estimated to impact about 1 million people in the US[ii] and over 5 million people worldwide[iii]. In patients with GA, single or multiple areas in the macular region of the retina become atrophic, forming distinct lesions that expand and coalesce over time. Enlargement of these lesions can lead to loss of vision and irreversible blindness. GA is often bilateral, meaning it occurs in both eyes. While there are approved treatments for wet AMD, there are currently no approved treatments for GA.

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 cardio-metabolic, liver, oncologic and retinal 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, with multiple programs in clinical development. 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,” “working to,” “advance,” “potential,” “target,” “believe,” “could,” “plans,” “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, enrollment and potential results of NGM’s Phase 2 CATALINA study of NGM621 for the treatment of patients with GA secondary to AMD; the potential of NGM621 as a best-in-class product candidate for the treatment of patients with GA; the potential therapeutic effects, benefits and dosing schedule of NGM621 and the role of NGM621 as a potential potent C3 inhibitor that may reduce disease progression in patients with GA; NGM’s plans to present the data from its completed Phase 1 study at an upcoming medical conference; 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 for, enrolling or completing clinical studies and the risk that NGM’s clinical 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’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, 2020 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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[ii] Friedman DS, O’Colmain BJ, Munoz B, et al. Prevalence of age-related macular degeneration in the United States. Arch Ophthalmol. 2004;122(4):564-572.

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