NGM Bio Announces Topline Results from the CATALINA Phase 2 Trial of NGM621 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration

Oct 17, 2022

- Trial did not meet primary endpoint of statistically significant rate of change in GA lesion area using slope analysis over 52 weeks for NGM621 versus sham
- NGM621 showed favorable safety and tolerability, with no evidence of increased CNV conversion and no treatment-related SAEs
- Additional analyses to be presented in early November at The Retina Society Annual Scientific Meeting
- NGM Bio to host conference call and webcast today at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., Oct. 17, 2022 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced topline efficacy and safety results from its randomized, double-masked, sham-controlled CATALINA Phase 2 trial of NGM621 in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). NGM621 is a humanized immunoglobulin G1 (IgG1) monoclonal antibody designed to inhibit activity of complement component 3 (C3). Over 52 weeks of treatment, NGM621 administered every four weeks (Q4W) (n=108) and every eight weeks (Q8W) (n=104) via intravitreal injection demonstrated a reduction in the rate of change in GA lesion area (slope) of 6.3% and 6.5%, respectively, compared to sham (n=106), which did not reach statistical significance in either arm. NGM621 demonstrated a favorable safety profile, with no evidence of increased choroidal neovascularization (CNV) conversions and numerically fewer cases of CNV in NGM621-treated patients compared to sham. In addition, there were no drug-related serious adverse events (SAEs).

“We’re disappointed that the CATALINA study did not meet its primary endpoint, particularly given the significant unmet medical need of patients impacted by GA,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. “We continue to evaluate various pre-specified secondary endpoints and post-hoc analyses. We expect these additional findings, as well as the absence of treatment-related CNV conversion and the overall clean safety profile NGM621 showed in CATALINA, to provide important information regarding the treatment of patients with GA.”

“Through data from CATALINA, I believe we can gain insights not only related to NGM621, but also importantly into strategies to optimize clinical development programs for the GA field more broadly. As we have seen repeatedly, there can be high variability in outcomes among trials of complement inhibitors for GA, and we are still learning how such variability impacts the evaluation of therapeutics for this devastating disease process,” said Charles C. Wykoff, M.D., Ph.D., Director of Research at Retina Consultants Texas and an investigator for the CATALINA study. “While the CATALINA trial did not meet its primary endpoint, the notable CNV finding combined with signals from secondary and exploratory analyses suggest the possibility that NGM621 may have a role in treating GA. I look forward to evaluating further details from this trial and presenting the findings at the upcoming Retina Society Annual Meeting in November.”

CATALINA Phase 2 Study Safety Findings

NGM621 demonstrated a favorable safety and tolerability profile, with no evidence of increased treatment-related CNV conversions compared to sham and numerically fewer cases of CNV in NGM621-treated patients compared to sham. There were also no cases of endophthalmitis (infection of the eye) or optic ischemic neuropathy, a low overall rate of inflammation and, overall, no treatment-related SAEs. The most frequently reported ocular adverse events were those most likely to be attributed to the intravitreal injection procedure or to GA worsening.

“On behalf of the entire NGM Bio team, I’d like to thank the investigators and clinical trial staff involved in this study, our employees who contributed to this tremendous effort and, most importantly, the patients who participated in the study to help advance our understanding of NGM621 as a potential treatment for GA. We recognize the significant unmet need of GA patients for effective treatment solutions, and we remain hopeful that NGM621 may have the potential to demonstrate future clinical benefit,” said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM Bio.

Conference Call / Webcast Details

NGM Bio will host a conference call and webcast with slide presentation at 8:00 a.m. ET (5:00 a.m. PT) today. To access the live webcast and slides, please visit the “Investors & Media” section of NGM Bio’s website at https://ir.ngmbio.com/. The webcast will be archived for 30 days.

NGM621 CATALINA Phase 2 Study Design

The Phase 2 CATALINA study enrolled 320 patients diagnosed with GA secondary to AMD in one or both eyes. The primary objectives of this multicenter, randomized, double-masked, sham-controlled study were to evaluate the efficacy and safety of NGM621 when given every four weeks or every eight weeks via intravitreal injections compared to sham injection control. Patients were randomized to one of four treatment groups in a ratio of 2:1:2:1 to receive intravitreal injections of NGM621 or sham injections every four weeks or every eight weeks for a total of 52 weeks with a final follow-up visit at 56 weeks. The primary efficacy endpoint was the rate of change in GA lesion area (slope), as measured by fundus autofluorescence imaging, over 52 weeks of treatment. The primary safety endpoints evaluated the incidence and severity of ocular and systemic adverse events from treatment with NGM621 compared to sham control.

Merck NGM621 Licensing Option

NGM621 falls within the scope of NGM Bio's collaboration with Merck. Under the terms of the collaboration, following the CATALINA Phase 2 proof-of-concept trial, Merck has a one-time option to a worldwide, exclusive license for NGM621 and its related compounds, either alone or bundled with two additional undisclosed pre-clinical ophthalmology compounds and their related compounds. Merck is required to make its option decision in approximately three months. If Merck does not exercise its one-time option for NGM621, then NGM Bio will retain worldwide rights to NGM621, with a low, single digit royalty obligation to Merck if NGM Bio or a partner commercializes the program.

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 NGM Bio

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, always led by biology and motivated by unmet patient need. Today, the company has seven programs in clinical development, including four in Phase 2 or 2b studies, including the recently completed NGM621 CATALINA trial, 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 "will," "may," "potential," "potentially," "hopeful," "future," "look forward," "continue," "promising," "possibility," "aspires," "aims", "expect" 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 expectation that additional findings, as well as the absence of treatment-related CNV conversion and the overall clean safety profile NGM621 showed in CATALINA, will provide important information regarding the treatment of patients with GA; the possibility that NGM621 may have a role in treating GA; the potential of NGM621 to demonstrate future clinical benefit; Merck's decision, or not, to exercise a one-time option to a worldwide, exclusive license for NGM621 and its related compounds, either alone or bundled with two additional undisclosed pre-clinical ophthalmology compounds and their related compounds and the timing of any such decision by Merck; NGM Bio's aspiration to operate one of the most productive research and development engines in the biopharmaceutical industry; 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 statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including the risk that NGM621 may be unable to demonstrate future clinical benefit in patients with GA, particularly in light of the failure to achieve the primary endpoint in the Phase 2 CATALINA study of NGM621; risks related to failure or delays in successfully initiating, enrolling, reporting data from or completing clinical studies, as well as the risks that results obtained in preclinical or clinical trials to date may not be indicative of results obtained in future trials and that post-hoc analyses performed after unmasking trial results can result in the introduction of bias, have other limitations and may not be predictive of results obtained in future trials; NGM Bio's reliance on its amended collaboration with Merck, including the risks that if Merck fails to exercise its option to license NGM621, NGM Bio would need to partner the NGM621 program and/or raise substantial additional capital in order to further clinical development of NGM621, if any, which NGM Bio may be unable to do in a timely manner or at all, which could delay or preclude the further development of and/or commercialization of NGM621; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, NGM Bio's business and operations, including NGM Bio's ability to timely supply, initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; NGM Bio's reliance on third-party manufacturers for its product candidates and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM Bio's cash resources and NGM Bio's need for additional capital; and other risks and uncertainties affecting NGM Bio and its development programs, including those discussed in the section titled "Risk Factors" in NGM Bio's

quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed with the Securities and Exchange Commission (SEC) on August 4, 2022 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.

Investor Contact:
Brian Schoelkopf
ir@ngmbio.com

Media Contact:
Liz Melone
lmelone@ngmbio.com