# NGM Bio Announces Presentation of Post-Hoc Analyses from CATALINA Phase 2 Trial of NGM621 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD) at The Retina Society Annual Scientific Meeting

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SOUTH SAN FRANCISCO, Calif., Nov. 03, 2022 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced the presentation of findings from post-hoc analyses of its randomized, double-masked, sham-controlled CATALINA Phase 2 trial of NGM621, a monoclonal antibody designed to inhibit activity of complement component 3 (C3), in patients with GA secondary to AMD at The Retina Society Annual Scientific Meeting taking place November 2 – 5, 2022 in Pasadena, Calif. The presentation, given by Charles C. Wykoff, M.D., Ph.D., Director of Research at Retina Consultants Texas and an investigator for the CATALINA trial, included a summary of topline findings, as previously reported by NGM Bio, in addition to results from post-hoc analyses undertaken to further interpret the CATALINA study results. A recording of the presentation given at the Retina Society meeting is available on NGM Bio's website at https://www.ngmbio.com/discovery-engine/publications/.

The primary efficacy endpoint of the CATALINA trial was the rate of change in GA lesion area (slope), as measured by fundus autofluorescence (FAF) imaging, over 52 weeks of treatment. As previously reported, 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.

"A closer, post-hoc look at the CATALINA data on a patient-by-patient level suggests that complex, challenging GA lesions coupled with apparent methodology limitations associated with FAF grading may have led to unanticipated variability," commented Dr. Wykoff. "Post-hoc analyses that attempted to minimize some of this variability have yielded encouraging findings that I believe warrant further evaluation."

One of the post-hoc analyses presented at the Retina Society meeting involved the evaluation of a sub-population of patients least likely to be impacted by FAF grading limitations: those in the middle two quartiles of a quartile analysis based on baseline lesion area. The patients in this sub-group had baseline GA lesions measuring 4.17 – 9.64 $mm^2$ as compared to study inclusion criteria of baseline GA area between ≥2.5 $mm^2$ and ≤17.5 $mm^2$. In this analysis, NGM621 demonstrated a reduction in the rate of change in GA lesion area (slope) of 21.9% (Q4W) (n=55) and 16.8% (Q8W) (n=52), compared to sham (n=53). Using MMRM analysis with the adjusted treatment arm, the reduction in change from baseline in GA at 52 weeks was 20.6% (Q4W) and 16.6.% (Q8W).

NGM621 was discovered by NGM Bio under its strategic collaboration with Merck, known as MSD outside the United States and Canada.

**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," "believe," "potential," "future," "encouraging," "promising," "aspires," "aims" 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: the potential for a future role for NGM621 to help address the significant unmet need for GA patients; the observation that challenging GA lesions coupled with potential methodology limitations associated with FAF grading may have led to unanticipated variability in the Phase 2 CATALINA results; the belief that the findings from post-hoc analyses of the Phase 2 CATALINA findings warrant further evaluation; 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; a potential future NGM partner for NGM621; 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, such as the Phase 2 CATALINA 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 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 in which case, NGM may not receive any return on its investment in 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 of its other product candidates; 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.

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