



NGM Bio Presents Preliminary Data from Phase 1 Monotherapy Dose Escalation Trial of NGM707 in Patients with Advanced or Metastatic Solid Tumors at 2022 ESMO-IO Annual Meeting

December 7, 2022

- NGM707 was generally well tolerated to the highest dose evaluated (1800 mg) in the monotherapy escalation; maximum tolerated dose was not reached
- Linear pharmacokinetics (PK) was observed at doses ≥ 200 mg, and analysis of peripheral immune cells demonstrated dose-dependent receptor occupancy (RO), with doses ≥ 200 mg maintaining full ILT2 and ILT4 RO for the entire dosing interval to date
- Potential proof-of-mechanism (myeloid reprogramming) was observed in peripheral blood and tumor biopsies
- Early signals of anti-tumor activity demonstrated across multiple tumor types. Of 24 response-evaluable patients as of November 23, 2022, best overall responses are partial response in 1 patient, stable disease in 6 patients and non-complete response/non-progressive disease in 1 patient
- NGM707, ILT2/ILT4 antagonist antibody, is the most advanced of three early clinical-stage product candidates in NGM Bio's myeloid checkpoint and reprogramming portfolio

SOUTH SAN FRANCISCO, Calif., Dec. 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 the presentation of preliminary data from the Phase 1 Part 1a monotherapy dose escalation arm of the ongoing Phase 1/2 trial of NGM707 in patients with advanced or metastatic solid tumors at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Annual Congress, which is taking place December 7 – 9, 2022 in Geneva, Switzerland. In the poster presentation titled, "First-in-Human Study of NGM707, an ILT2/ILT4 Dual Antagonist Antibody in Advanced or Metastatic Solid Tumors: Preliminary Monotherapy Dose Escalation Data" (#174P), NGM707 was generally well tolerated across all dose cohorts and demonstrated promising early signals of anti-tumor activity. Of 24 response-evaluable patients in the Part 1a arm, best overall responses as of November 23, 2022 are partial response in one patient, stable disease in six patients and non-complete response/non-progressive disease in one patient. Six patients had reduced target lesion size including a maximum decrease in one patient of 70%. A copy of the presentation presented at the ESMO I-O Annual Congress is available on NGM Bio's website at <https://www.ngmbio.com/discovery-engine/publications/>.

The Phase 1 portion of the ongoing NGM707 trial includes a monotherapy dose escalation arm (Part 1a) and a dose-finding arm in combination with pembrolizumab (KEYTRUDA®) (Part 1b). The Phase 2 portion of the trial will include expansion cohorts of patients treated with NGM707 in combination with KEYTRUDA (Part 2b) in several advanced solid tumor types. The Part 1a arm enrolled patients into escalating NGM707 dose cohorts (6 mg to 1800 mg) administered intravenously every three weeks. Enrolled patients received a median of four prior lines of therapy, and all had metastatic disease. Primary objectives in the Phase 1 portion are to assess safety and tolerability of NGM707 and to identify Phase 2 doses. Secondary/exploratory objectives include assessment of PK/biomarker correlation, immunogenicity, and preliminary antitumor activity per RECIST v1.1.

As of a November 23, 2022 data cut-off, 34 patients have been enrolled in the monotherapy dose escalation. Of 24 response-evaluable patients (those completing at least one on-treatment scan), best overall responses are partial response (PR) in one patient, stable disease in six patients and non-complete response/non-progressive disease in one patient. Six of the 24 response-evaluable patients experienced target lesion reduction. The patient experiencing the PR had a target lesion decrease of 70%, along with a reduction and/or elimination of non-target lesions. These responses were seen across five distinct tumor types. Preliminary evidence of potential myeloid reprogramming was observed in peripheral non-classical monocytes as well as in tumor biopsies, with reduction of the M2 macrophage marker CD163 observed post-treatment. Treatment-related adverse events (TRAEs) occurred in 47% of patients, with 9% of patients experiencing Grade ≥ 3 TRAEs. One dose-limiting toxicity of pneumonitis (G5) in a patient with pulmonary metastasis was observed at NGM707 600 mg. A maximum tolerated dose was not reached.

As of November 23, 2022, four patients remain on NGM707 monotherapy treatment in the Part 1a arm, including the patient experiencing the PR. Enrollment is ongoing in the Part 1b arm evaluating NGM707 in combination with KEYTRUDA. NGM Bio anticipates enrolling approximately 220 patients in the Phase 1/2 trial of NGM707.

"NGM707 is designed to reprogram immune-suppressive ILT4- and ILT2-expressing myeloid cells and ILT2-expressing lymphoid cells in the tumor microenvironment into immune-stimulatory cells that will promote anti-tumor activity. We're pleased to present these initial data demonstrating a favorable tolerability profile for NGM707 as well as early, yet promising signals that this mechanistic approach may translate to clinical benefit," said Dan Kaplan, Ph.D., Head of Translational Immuno-Oncology at NGM Bio. "We're particularly encouraged to see clinical benefit in certain patients in response to monotherapy treatment with NGM707, and we look forward to evaluating NGM707's potential effect when combined with T cell checkpoint inhibition in Part 1b of the study, which is now underway."

About NGM707

ILT2 and ILT4, inhibitory receptors with enriched expression on myeloid cells in the tumor microenvironment, are myeloid checkpoints that may enable certain tumors to evade immune detection, thereby suppressing patients' anti-tumor responses. NGM707 is being developed with the goal of improving patient immune response to tumors by inhibiting both ILT2 and ILT4. By inhibiting both ILT2 and ILT4, NGM707 may be able to overcome the potential redundant role the two receptors play where they are co-expressed in myeloid cells and reprogram those cells to enhance T cell activity

and proliferation. In addition, ILT2 blockade may drive further benefit through reducing suppression in certain lymphoid cells capable of directly attacking tumor cells.

About NGM Bio's Oncology Portfolio

NGM Bio's currently disclosed oncology product candidates are all derived from the company's in-house discovery engine and are wholly owned by NGM Bio. These oncology programs include: NGM120, a GFRAL antagonist antibody in a Phase 2 trial for the treatment of metastatic pancreatic cancer; NGM707, an ILT2/ILT4 (LILRB1/LILRB2) dual antagonist antibody in a Phase 1/2 trial for the treatment of advanced or metastatic solid tumors; NGM831, an ILT3 (LILRB4) antagonist antibody in a Phase 1 trial in advanced solid tumors; and NGM438, a LAIR1 antagonist antibody in a Phase 1 trial in advanced solid tumors.

Abbreviations (in Alphabetical Order)

GFRAL= Glial Cell-derived Neurotrophic Factor Receptor Alpha-like; ILT2=Immunoglobulin-Like Transcript 2; ILT3=Immunoglobulin-Like Transcript 3; ILT4=Immunoglobulin-Like Transcript 4; LAIR1= LAIR1=Leukocyte-Associated Immunoglobulin-Like Receptor 1; LILR=Leukocyte Immunoglobulin-Like Receptor [ILT2 = LILRB1, ILT3=LILRB4, ILT4=LILRB2]; LIR=Leukocyte Immunoglobulin-Like Receptor.

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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," "promising," "plan," "preliminary," "anticipates," "aspires," "aims," "designed to" 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 proof-of-mechanism and anti-tumor activity of NGM707, alone and in combination with KEYTRUDA; the potential of NGM Bio's immune-oncology product candidates, NGM707, NGM831 and NGM438, to block myeloid checkpoints to reprogram suppressive myeloid cells in the tumor microenvironment, including NGM707's potential to reprogram immune-suppressive ILT4- and ILT2-expressing myeloid cells and ILT2-expressing lymphoid cells in the tumor microenvironment into immune-stimulatory cells that will promote anti-tumor activity; the potential effects of blocking/inhibiting ILT and ILT4 together and separately; the ability to enroll patients in the Phase 1/2 trial of NGM707; 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, the risk that results obtained in preclinical or clinical trials to date with NGM707 may not be indicative of results obtained in ongoing or future trials and that NGM Bio's product candidates may otherwise not be tolerable and effective treatments in their planned indications; 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 successfully initiating, enrolling, reporting data from or completing clinical studies, as well as 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 September 30, 2022 filed with the United States Securities and Exchange Commission (SEC) on November 3, 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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