NGM Bio Announces Initiation of Phase 1/2 Clinical Study of NGM707 for the Treatment of Advanced Solid Tumors

July 7, 2021

--NGM707, a ILT2/ILT4 dual antagonistic antibody, is engineered to reverse myeloid suppression with the goal of improving patient immune responses to tumors--

--Study to evaluate potential of NGM707 in patients with tumor types with elevated expression of ILT2 and ILT4 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab)--

--Approximately 180 patients expected to be enrolled in the Phase 1/2 Study--

SOUTH SAN FRANCISCO, Calif., July 07, 2021 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, announced it has dosed the first patient in a Phase 1/2 study to evaluate the efficacy, safety and pharmacokinetics/pharmacodynamics of NGM707 when given alone or in combination with KEYTRUDA® (pembrolizumab), an anti- PD-1 antibody. NGM707 is a novel dual antagonist antibody that inhibits the Immunoglobulin-like Transcript 2 (ILT2) and Immunoglobulin-like Transcript 4 (ILT4) receptors. NGM707 originated from NGM's in-house discovery engine. The program follows NGM120, a glial cell-derived neurotrophic factor alpha-like (GFRAL) antagonistic antibody, which is currently in a Phase 2 study in patients with metastatic pancreatic cancer, as the second NGM wholly owned oncology candidate in the clinic.

"NGM707 is designed to improve tumor responses in cancer patients by both reprogramming immuno-suppressive myeloid cells through ILT4 inhibition and by further stimulating the activity of myeloid and lymphoid cells through ILT2 inhibition. As ILT4 inhibition continues to gain interest as a potentially important oncology strategy, our research suggests that NGM707's novel dual blockade of ILT4 and ILT2 may yield enhanced anti-tumor activity," said Alex DePaoli, M.D., Senior Vice President, Chief Translational Officer at NGM. "As a result, we believe NGM707 offers a potentially compelling treatment profile and could represent an important therapeutic advancement for patients with cancer."

ILT2 and ILT4 are receptors overexpressed on myeloid cells in the tumor microenvironment. These receptors are implicated in suppressing anti-tumor immune responses and may represent myeloid checkpoints that enable certain tumors to evade immune detection. NGM707 was designed with the goal of improving patient immune responses to tumors by inhibiting both the ILT2 and ILT4 receptors. In preclinical studies of NGM707, NGM has demonstrated that blockade of ILT4 reverses myeloid cell immune suppression, while blockade of ILT2 promotes natural killer (NK) and CD8+ T-cell killing of tumor cells and activates macrophage phagocytosis of tumor cells. Furthermore, preclinical studies of NGM707 have shown that the dual blockade of ILT2 and ILT4 may be more effective than blockade of either receptor alone in reversing suppression of Fc receptor signaling. In addition, preclinical work has shown that NGM707 in combination with pembrolizumab acts additively to increase T-cell activation and cytokine secretion.

"As we continue to look for novel agents applicable to a broad range of solid tumors and approaches with stronger anti-tumor immune responses, a therapeutic that addresses key myeloid checkpoint resistance mechanisms could represent a significant advancement for cancer patients," said Patricia LoRusso, DO, Professor of Medicine (Medical Oncology); Associate Cancer Center Director, Experimental Therapeutics, Yale University. "NGM707, by reversing myeloid and lymphoid checkpoints, is a promising approach that can potentially help these patients. We look forward to enrolling patients in this Phase 1/2 study and understanding how NGM707's preclinical benefits may translate to patients in the clinical setting."

About the NGM707 Phase 1/2 Study Design

The Phase 1 portion (n=60) of the study includes a monotherapy dose escalation arm (Part 1a) and a dose-finding arm in combination with KEYTRUDA (Part 1b) to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and recommended Phase 2 dose of NGM707 alone and administered in combination with KEYTRUDA. Parts 1a and 1b may also provide the opportunity to identify preliminary efficacy signals. The Phase 2 portion (n=120) of the study employs a basket design that will include expansion cohorts of patients treated with NGM707 monotherapy (Part 2a) or NGM707 in combination with KEYTRUDA (Part 2b) to evaluate the efficacy, safety and tolerability of NGM707 alone or in combination with KEYTRUDA. Preliminary evidence of anti-tumor response in the Phase 2a portion will be evaluated using objective response rate, duration of response and progression free survival, while the Phase 2b portion will also evaluate overall survival. Both the Phase 1 and Phase 2 portions of the study will provide the opportunity to evaluate correlations between biomarker changes and clinical outcomes.

This study will enroll adult patients with advanced or metastatic solid tumors with elevated expression of ILT2 and ILT4, including patients with non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), renal cell carcinoma (RCC), mesothelioma, glioblastoma, melanoma, pancreatic, gastric, biliary duct, breast, ovarian, cervical, endocervical, colorectal and esophageal cancer.

For additional information about the study, please click here to visit the listing on clinicaltrials.gov.

About NGM's Oncology Portfolio

NGM's currently disclosed oncology product candidates are all derived from the company's in-house discovery engine and are wholly owned by NGM. These oncology programs include: NGM120, GFRAL antagonistic antibody in Phase 2 study for the treatment of metastatic pancreatic cancer; NGM707, an ILT2/ILT4 (also known as Immunoglobulin-Like Receptor subfamily B (LILRB1/LILRB2)) dual antagonist antibody in a Phase 1/2 study for the treatment of advanced solid tumors; and NGM438, a Leukocyte-associated immunoglobulin-like receptor 1 (LAIR1) antagonist antibody, planned to enter into a Phase 1 study in advanced solid tumors in the first half of 2022.

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 retinal diseases, cancer, and liver and metabolic 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. All of our therapeutics have been generated by our in-house discovery engine; today, we have six disclosed programs, including four in Phase 2 or 2b studies, across three therapeutics areas. 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 “may,” “could,” “will,” “planned,” “believe,” “expected” “promising,” “opportunity,” “look forward,” “goal,” “designed to,” “suggests,” “aspire,” “potential,” “potentially” 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 therapeutic potential and potential benefits of NGM707, including NGM707’s potential in patients with tumor types with elevated expression of ILT2 and ILT4 and NGM’s belief that NGM707 could represent an important therapeutic advancement for patients with cancer; the potential of NGM707’s novel dual blockade of ILT4 and ILT2 to yield enhanced anti-tumor activity and be more effective than blockade of either receptor alone in reversing suppression of Fc receptor signaling; expected enrollment in the Phase 1/2 Study of NGM707; the design of the Phase 1/2 Study of NGM707; the planned initiation of a Phase 1 study of NGM438 and the anticipated timing thereof; 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 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 risks related to failure or delays in successfully initiating, enrolling or completing clinical studies, the risk that NGM’s ongoing or future clinical studies in humans may show that NGM707, NGM120 and/or NGM438 are not tolerable and effective treatments for cancer patients or that the effects of inhibiting both the ILT2 and ILT4 receptors are otherwise different than anticipated, and the risk that success in preclinical studies does not ensure that clinical trials evaluating NGM707 or NGM’s other product candidates will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of such product candidates; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, NGM’s business and operations, including NGM’s ability to timely supply, initiate, enroll and complete its ongoing and future clinical studies; the time-consuming and uncertain regulatory approval process; NGM’s reliance on third-party manufacturers for NGM707, NGM120, NGM438 and its other product candidates; the sufficiency of NGM’s cash resources, including to fund its wholly owned programs, and its need for additional capital; and other risks and uncertainties affecting NGM and its development programs, as well as those discussed in the section titled “Risk Factors” in NGM’s quarterly report on Form 10-Q for the quarter ended March 31, 2021 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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