NGM Bio Announces Clinical Trial Collaboration with Merck Related to Ongoing Phase 1/2 Trial of NGM707, an ILT2/ILT4 Dual Antagonist Antibody, in Combination with Merck's KEYTRUDA® (pembrolizumab)

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- NGM entered into a clinical trial collaboration and supply agreement with Merck to evaluate the potential of NGM707 in combination with KEYTRUDA for the treatment of patients with advanced or metastatic solid tumors
- NGM707 is part of NGM's wholly-owned portfolio of immuno-oncology programs focused on releasing myeloid checkpoints to reprogram myeloid cells to reverse immune suppression
- ILT2 and ILT4, upregulated in certain tumor types, are believed to serve as myeloid checkpoints, helping tumors evade immune detection
- NGM707 is designed to reprogram ILT4-expressing myeloid cells and stimulate the activity of ILT2 expressing myeloid and lymphoid cells to enhance anti-tumor immunity
- NGM's additional myeloid checkpoint inhibitor candidates include NGM831 and NGM438, ILT3 and LAIR1 antagonist antibodies

SOUTH SAN FRANCISCO, Calif., Dec. 06, 2021 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced a clinical trial collaboration and supply agreement with Merck (known as MSD outside of the United States and Canada) to evaluate NGM707, NGM's wholly-owned novel ILT2/ILT4 dual antagonist antibody, in combination with Merck's anti-PD-1 therapy, KEYTRUDA. NGM is currently enrolling patients in the Phase 1/2 trial, initiated in June 2021, to evaluate the potential of NGM707 as a monotherapy and in combination with KEYTRUDA in adult patients with advanced or metastatic solid tumors with elevated expression of ILT2 and ILT4.

"ILT2 and ILT4 are among a group of myeloid immune checkpoint receptors that are upregulated in patients who do not respond to T-cell checkpoint therapy, suggesting that they are potential resistance mechanisms that generate an immunosuppressive state in the tumor microenvironment. We're excited by the unique profile of NGM707 in the myeloid checkpoint inhibition space. Our preclinical studies suggest that NGM707's dual blockade of ILT2 and ILT4 may be more effective than blockade of either receptor alone in reversing myeloid based immune suppression, which is known to limit anti-tumor immunity," said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM Bio.

Dr. Lieu continued, "We're pleased to enter into this agreement with Merck for our ongoing Phase 1/2 trial of NGM707. In preclinical models, we have demonstrated that NGM707 in combination with KEYTRUDA acts additively to increase T cell activation and cytokine secretion. We look forward to evaluating how these mechanisms of action translate in the clinic to potentially enable broader and deeper anti-tumor immune responses, bringing the promise of immunotherapy to more cancer patients."

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 response. 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 when 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.

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

About the NGM707 Phase 1/2 Trial Design

The Phase 1 portion (n≅60) of the trial includes a monotherapy dose escalation arm (Part 1a) and a dose-finding arm in combination with KEYTRUDA® (pembrolizumab) (Part 1b). The Phase 2 portion (n≅120) of the trial will employ a basket design that will include expansion cohorts of patients treated with NGM707 monotherapy (Part 2a) or NGM707 in combination with KEYTRUDA (Part 2b) in a variety of selected solid tumor types.

For additional information about the trial, including types of cancers being evaluated and other eligibility criteria, 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, 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 solid tumors; NGM831, an ILT3 (LILRB4) antagonist antibody, planned to enter into a Phase 1 trial in advanced solid tumors in the first half of 2022; and NGM438, a LAIR1 antagonist antibody, also planned to enter into a Phase 1 trial in advanced solid tumors in the first half of 2022.

Abbreviations (in Alphabetical Order)
GFRAL=Glial Cell-Derived Neurotrophic Factor Receptor Alpha-Like; ILT2=Immunoglobin-Like Transcript 2; ILT3=Immunoglobin-Like Transcript 3; ILT4=Immunoglobin-Like Transcript 4; LAIR1=Leukocyte-Associated Immunoglobulin-Like Receptor 1; LILR= Leukocyte Immunoglobin-Like Receptor [ILT2 = LILRB1, ILT3=LILRB4, ILT4=LILRB2]

About NGM
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 therapeutic candidates have been generated by our in-house discovery engine; today, we have seven disclosed programs, including four in Phase 2 or 2b studies, across three therapeutic 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 "will," "may," "believed," "designed," "suggesting," "suggest," "look forward," "potentially," "potential," "promise," "goal," "planned," "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: the therapeutic potential of NGM707, including the potential of NGM707 in combination with KEYTRUDA to potentially enable broader and deeper anti-tumor immune responses; Merck supplying KEYTRUDA to NGM under the clinical trial collaboration; the design of the Phase 1/2 trial of NGM707; the ability of NGM707 to inhibit ILT2 and ILT4 and the potential benefits of ILT2 and ILT4 inhibition; the planned commencement of Phase 1 clinical trials of NGM831 and 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, reporting data from or completing clinical studies, as well as the risks that results obtained in clinical trials to date may not be indicative of results obtained in ongoing or future trials and that NGM's product candidates, including NGM707, may otherwise not be tolerable and effective treatments in their planned indications; NGM's ability to maintain its clinical trial collaboration with Merck, including the risk that if Merck were to breach or terminate the clinical trial collaboration, the evaluation of NGM707 in combination with KEYTRUDA could be delayed, perhaps substantially, and NGM's costs to conduct the Phase 1/2 trial of NGM707 could substantially increase; 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 trials; the time-consuming and uncertain regulatory approval process; NGM's reliance on third-party manufacturers for NGM707, NGM831 and NGM438 and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM's cash resources, including to fund its wholly-owned programs such as NGM707, and NGM's need for additional capital; and other risks and uncertainties affecting NGM and its development programs, including those discussed in the section titled "Risk Factors" in NGM's quarterly report on Form 10-Q for the quarter ended September 30, 2021 filed with the United States Securities and Exchange Commission (SEC) on November 4, 2021 and future filings and reports that NGM makes from time to time with the SEC. 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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