

# NGM Bio Outlines 2022 Strategic Priorities Across Its Portfolio of Clinical-Stage Oncology, Retinal and Liver and Metabolic Programs

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- After a transformative year in 2021, NGM Bio enters 2022 with a diverse pipeline of seven disclosed programs, including four programs in Phase 2 trials and a wholly-owned oncology portfolio
- Anticipated milestones in 2022 include:
  - Topline data readout from the Phase 2 CATALINA trial of NGM621 in patients with geographic atrophy expected in the fourth guarter of 2022
  - Phase 1a data readout from the ongoing trial of NGM707 monotherapy in patients with advanced solid tumors expected in the second half of 2022
  - Additional data readouts from the Phase 1a/1b trial of NGM120 expected in the second half of 2022
  - Initiation of Phase 1 trial for NGM831 expected in the first quarter of 2022; Initiation of Phase 1 trial for NGM438 expected in the second quarter of 2022

SOUTH SAN FRANCISCO, Calif., Jan. 10, 2022 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today provided an overview of highlights from 2021 and its strategic priorities for 2022.

"2021 was a breakthrough year for NGM Bio as the power of our internal discovery engine is now readily observable in the depth and breadth of our clinical-stage portfolio of programs," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. "Beyond the progress we made across our programs, we also secured worldwide rights to our portfolio of oncology programs and have been urgently mobilizing resources to advance them into clinical proof-of-concept trials."

Dr. Woodhouse continued, "Over the next 12 months, we anticipate reaching multiple milestones across our advancing pipeline, including expected readouts of topline data from our Phase 2 CATALINA study of NGM621 in patients with geographic atrophy, additional data from our Phase 1a/1b study of NGM120 in patients with advanced solid tumors and pancreatic cancer and initial Phase 1a clinical data for NGM707, the lead asset in our myeloid reprogramming portfolio, in patients with advanced solid tumors."

#### 2021 Highlights

NGM Bio's key 2021 highlights included:

#### Oncology

- Presented preliminary findings from an ongoing, open-label Phase 1a/1b dose escalation trial of NGM120, a novel GFRAL antagonist antibody product candidate, in patients with advanced solid tumors at the European Society for Medical Oncology (ESMO) Virtual Congress in September 2021
- Initiated a Phase 1/2 trial of NGM707, a dual ILT2/ILT4 antagonist antibody product candidate, as a monotherapy and in combination with KEYTRUDA® (pembrolizumab), in patients with advanced solid tumors in June 2021
- Initiated the Phase 2 placebo-controlled PINNACLES trial of NGM120 in combination with gemcitabine and Nab-paclitaxel as a first-line treatment in patients with metastatic pancreatic cancer in March 2021
- Disclosed our fourth oncology development candidate, NGM831, an ILT3 antagonist antibody product candidate, in August 2021, further establishing NGM Bio's growing portfolio of development candidates focused on tumor stroma biology and myeloid reprogramming
  - The disclosure of NGM831 coincided with a publication in *Cancer Immunology Research* revealing the discovery of one of ILT3's functional ligands, fibronectin, a key component of the tumor stroma

## **Retinal Diseases**

• Completed enrollment of the Phase 2 CATALINA trial of NGM621, a monoclonal antibody product candidate against complement C3, in patients with geographic atrophy secondary to age-related macular degeneration in July 2021, enrolling 320 patients at 65 sites in the United States

• Presented the results of a Phase 1 trial of NGM621 in patients with geographic atrophy at the Angiogenesis, Exudation, and Degeneration Annual Meeting and the Association for Research in Vision and Ophthalmology (ARVO) 2021 Annual Meeting and published the data in the *American Journal of Ophthalmology* 

## Liver and Metabolic Diseases

- Merck Sharp & Dohme Corp. (Merck) continued to progress enrollment in a global Phase 2b trial of MK-3655 for the treatment of non-cirrhotic (F2/F3) NASH
- Decided to discontinue development of aldafermin in non-cirrhotic (F2/F3) NASH following the announcement that the ALPINE 2/3 Phase 2b trial of aldafermin in F2/F3 NASH did not meet its primary endpoint, allowing for the reallocation of resources towards advancing our oncology and other programs
- Continued to enroll patients in ALPINE 4, the Phase 2b trial of aldafermin in patients with compensated NASH cirrhosis (F4 NASH)

# Corporate Highlights

- Renegotiated our collaboration agreement with Merck to regain worldwide rights to our disclosed oncology programs and to narrow the scope of the collaboration to focus primarily on the discovery and development of novel medicines for unmet patient needs in retinal and cardiovascular and metabolic diseases, including heart failure. Merck retains an option to license those programs being advanced under the amended collaboration. Prior to Merck initiating any Phase 3 study of a collaboration program licensed by Merck, we may elect to receive milestone or royalty payments or, in certain cases, co-fund development and participate in a global cost and profit share arrangement of up to 50%. We also have the option to participate in the co-promotion of any co-funded program in the United States. In 2022, the funding we receive from Merck will be substantially lower than the research funding provided by Merck previously due to the narrower scope of the amended collaboration
- Entered into a clinical trial collaboration and supply agreement with Merck related to NGM Bio's ongoing Phase 1/2 trial of NGM707 in combination with Merck's KEYTRUDA® (pembrolizumab)<sup>1</sup> in December 2021
- Roger M. Perlmutter, M.D., Ph.D. joined NGM Bio's board of directors in June 2021

# 2022 Strategic Priorities and Anticipated Clinical Milestones

NGM Bio's strategic priorities and anticipated key clinical milestones in 2022 include:

## Oncology

- Initiation of a Phase 1 trial of NGM831 for the treatment of patients with advanced solid tumors expected in the first quarter of 2022
- Initiation of a Phase 1 trial of NGM438, a LAIR1 antagonist antibody, for the treatment of patients with advanced solid tumors expected in the second quarter of 2022
- Initial data from the Phase 1a trial of NGM707 monotherapy in patients with advanced solid tumors expected in the second half of 2022
- Additional data from the ongoing Phase 1a/1b trial of NGM120 in patients with cancer and cancer-related cachexia expected in the second half of 2022

## Retinal Diseases

• Topline data readout from the Phase 2 CATALINA trial of NGM621 in patients with geographic atrophy expected in the fourth quarter of 2022

## Liver and Metabolic Diseases

- Final patient enrollment expected in the first quarter of 2022 for ALPINE 4, the Phase 2b trial of aldafermin in patients with F4 NASH
- Continued enrollment by Merck in ongoing, global Phase 2b trial of MK-3655 in patients with non-cirrhotic (F2/F3) NASH

As previously announced, David J. Woodhouse, Ph.D., Chief Executive Officer of NGM Bio, will present an overview of the company and a business update at the 40th Annual J.P. Morgan Healthcare Conference on Thursday, January 13th at 7:30 AM PST/10:30 AM EST. For more information, visit <a href="https://ir.ngmbio.com/news-releases">https://ir.ngmbio.com/news-releases</a>.

## About NGM Biopharmaceuticals, Inc.

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, with a disease-agnostic mindset, always led by biology and motivated by unmet patient need. Today, the company has seven disclosed programs, including four in Phase 2 or 2b studies, across three therapeutic areas: cancer, retinal diseases and liver and metabolic diseases. Visit us at <u>www.ngmbio.com</u> for more information.

<sup>1</sup>KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

#### Abbreviations (in Alphabetical Order)

F2/F3/F4 = stage 2 or 3 or 4 liver fibrosis; 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]; NASH=non-alcoholic steatohepatitis

#### **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," "expected," "anticipates," "preliminary," "enable," "believed," "designed," "suggesting," "suggest," "look forward," "potentially," "potential," "promise," "goal," "planned," "plans," "aspire," "aim" 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 product candidates, including the potential of NGM Bio's oncology product candidates to become next-generation treatment options; NGM Bio's belief that myeloid cell reprogramming can be an important additional approach to augment anti-tumor immunity and the potential of its product candidates to harness that biology; the design of NGM Bio's and Merck's clinical trials of NGM Bio's product candidates; the encouraging preliminary signals of anti-cancer activity in the Phase 1a/1b study of NGM120; the planned commencement of a Phase 1 clinical trials of NGM831 and NGM438 and the anticipated timing thereof; the availability and anticipated timing of data from the Phase 2 CATALINA study of NGM621 and the Phase 1a study of NGM707; the continuation of the Phase 2b ALPINE 4 trial of aldafermin; potential activities, and the potential receipt of milestone and royalty payments, under NGM Bio's amended collaboration with Merck; 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 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 Bio's product candidates may otherwise not be tolerable and effective treatments in their planned indications; NGM Bio's ability to maintain its amended collaboration with Merck, including the risk that if Merck were to breach or terminate the amended collaboration or Merck's development funding obligations, NGM Bio would not obtain all of the anticipated financial and other benefits of the amended collaboration, and the development and/or commercialization of NGM Bio's product candidates within the scope of the amended collaboration could be delayed, perhaps substantially; 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, including to fund its wholly-owned programs, and NGM'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 guarter 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 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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