



## NGM Bio Outlines Corporate Strategy and Provides Guidance on Key Priorities

January 9, 2023

- NGM Bio's three-pronged corporate strategy includes the following components:
  - Focus internal clinical development efforts on solid tumor oncology portfolio
  - Generate next-generation biologics through prolific in-house discovery engine
  - Seek partners for other NGM-discovered programs including aldafermin, NGM621 and NGM936
- 2023 key priority to advance signal-seeking trials of myeloid checkpoint inhibitor immuno-oncology programs NGM707, NGM831 and NGM438

SOUTH SAN FRANCISCO, Calif., Jan. 9, 2023 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today is providing an overview of highlights from 2022 and outlining its 2023 corporate priorities.

"In 2022, NGM Bio sharpened its focus on oncology solid-tumor clinical development. We reported promising preliminary data from our first myeloid checkpoint inhibitor program, NGM707, and advanced our additional myeloid checkpoint inhibitor programs, NGM438 and NGM831, into the clinic," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio.

Dr. Woodhouse continued, "Our strategy in 2023 is to focus our clinical development efforts on our portfolio of four clinical-stage oncology programs while operating our prolific drug discovery engine to generate next-generation biologic therapeutics. For our programs outside this area of focus, in retinal disease and NASH, we will seek development partners with relevant domain expertise. We're committed to developing transformative therapeutics for patients and energized by the opportunities we see in this next chapter of the NGM Bio story."

### **Key 2022 Activities**

#### ***Oncology***

##### Myeloid Checkpoint Inhibitor Portfolio

- Presented preliminary data from the Phase 1a monotherapy portion of the Phase 1/2 trial of NGM707, an ILT2/ILT4 antagonist antibody product candidate, in patients with advanced or metastatic solid tumors at the 2022 European Society of Medical Oncologists (ESMO) I-O Annual Congress in Q4 2022. NGM707 was generally well tolerated, potential proof-of-mechanism (myeloid reprogramming) was observed in peripheral blood and tumor biopsies and early signals of anti-tumor activity were demonstrated across multiple tumor types. As of a November 23, 2022 cut-off there were 24 response-evaluable patients and best overall responses were partial response in one patient, stable disease in six patients and non-complete response/non-progressive disease in one patient.
- Initiated a Phase 1 trial of NGM831, an ILT3 antagonist antibody product candidate, in Q1 2022 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.
- Initiated a Phase 1 trial of NGM438, a LAIR1 antagonist antibody product candidate, in Q2 2022 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.

##### Other Oncology Programs

- Presented updated preliminary findings from ongoing Phase 1a and Phase 1b cohorts evaluating NGM120, an antagonist antibody that binds GFRAL and inhibits GDF15 signaling, for the treatment of cancer at the 2022 ESMO Annual Congress and at the 2022 American Association for Cancer Research (AACR) Special Conference: Pancreatic Cancer in Q3 2022.
- Presented preclinical data on NGM Bio's first disclosed bispecific program, NGM936, an ILT3 x CD3 bispecific antagonist antibody product candidate designed for the treatment of AML and multiple myeloma, at the 2022 American Society of Hematology (ASH) Annual Meeting in Q4 2022.

#### ***Retinal Diseases***

- Completed the Phase 2 CATALINA trial of NGM621, a monoclonal antibody product candidate engineered to potently inhibit complement C3 for patients with geographic atrophy (GA) secondary to advanced macular degeneration, which did not meet its primary endpoint of a statistically significant rate of change using slope analysis in GA lesion area over 52

weeks for NGM621 versus sham. Presented additional findings from post-hoc analyses from the CATALINA trial at The Retina Society Annual Scientific Meeting in Q4 2022.

#### **NASH**

- Completed enrollment in ALPINE 4, the Phase 2b trial of aldafermin, an engineered FGF19 analog product candidate, in patients with compensated NASH cirrhosis (F4 NASH) in Q1 2022.
- Received notification from Merck of its decision to terminate the Phase 2b trial of MK-3655 in patients with NASH and liver fibrosis stage 2 or 3 and pursue other priorities. This decision was based on the results of an interim analysis of safety and reduction in liver fat at Week 24. Although it was not the primary endpoint of the trial, the percent reduction from baseline in liver fat for MK-3655, while greater than placebo across multiple dose arms, did not reach Merck's threshold for continuing the trial. The trial was not discontinued for safety concerns.

#### **Corporate**

- Cash runway is expected to be sufficient to fund operations into the fourth quarter of 2024.

#### **2023 Strategic Priorities**

##### **Oncology**

- Advance the ongoing Phase 1/2 signal-seeking trial of NGM707 and the ongoing Phase 1 signal-seeking trials of NGM831 and NGM438, all being studied in patients with advanced solid tumors

#### **NASH**

- Read out topline data from ALPINE 4, the Phase 2b trial of aldafermin in patients with F4 NASH, in Q2 2023

#### **Business Development**

- Consistent with NGM Bio's business model since inception, business development will remain a key priority to allow the company to focus development and financial resources on oncology clinical development and new molecule generation. NGM Bio will seek partners for the following programs:
  - Aldafermin, an engineered FGF19 analog product candidate, designed for the treatment of patients with NASH and/or diseases related to bile acid dysregulation
  - NGM621, a monoclonal antibody product candidate engineered to potently inhibit complement C3, designed for the treatment of patients with GA secondary to advanced macular degeneration
  - NGM936, an ILT3 x CD3 bi-specific antagonist antibody product candidate, designed for the treatment of patients with AML and multiple myeloma

Visit [www.ngmbio.com/discovery-engine/publications/](http://www.ngmbio.com/discovery-engine/publications/) to view all of NGM Bio's posters and presentations.

#### **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, always led by biology and motivated by unmet patient need. Today, the company has five programs in active clinical development. Visit us at [www.ngmbio.com](http://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.

#### **Abbreviations (in Alphabetical Order)**

AML=Acute Myeloid Leukemia; C3=Complement Component 3; F4 = stage 4 liver fibrosis; FGF19= Fibroblast growth factor 19; GDF15=Growth Differentiation Factor 15; 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=Leukocyte-Associated Immunoglobulin-Like Receptor 1; 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," "expect," "seek," "promising," "potential," "plan," "engineered to," "aim," "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 NGM Bio's product candidates; NGM Bio's continued pipeline development and research and development output; NGM Bio's expectation of providing updates and meeting milestones, including the availability and anticipated timing of a topline data readout from the Phase 2b trial of aldafermin in the second quarter of 2023; the ability of NGM Bio to find partners for aldafermin, NGM621 and NGM936; the sufficiency of NGM Bio's cash resources 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; 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 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 risk that if Merck elects to terminate the amended collaboration agreement as it relates to MK-3655 and its related compounds, the license rights previously granted to Merck with respect to MK-3655 and its related compounds would revert to NGM Bio; 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; NGM Bio's ability to partner certain programs and 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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