NGM Bio Announces Presentation of Data from Phase 2 Investigator-Sponsored Trial of Aldafermin for the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) and Bile Acid Malabsorption (BAM) at Digestive Disease Week 2023

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- Aldafermin demonstrated statistically significant reductions in serum 7αC4 (a marker of bile acid synthesis) and fecal bile acids versus placebo in patients with idiopathic BAM with IBS-D
- Around 25-50% of patients with diarrhea-predominant IBS (or IBS-D) have evidence of BAM
- Findings complete an extensive clinical data package that NGM Bio will leverage to seek a development partner for aldafermin; NGM Bio's internal development efforts will continue to focus on its portfolio of four clinical-stage oncology product candidates

SOUTH SAN FRANCISCO, Calif., May 08, 2023 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today announced that results of a Phase 2 investigator-sponsored trial of aldafermin for the treatment of patients with idiopathic BAM with IBS-D were presented at Digestive Disease Week 2023.

IBS is a gastrointestinal disorder characterized by recurrent abdominal pain and altered bowel movements. An estimated 25 – 50% of patients with diarrhea-predominant IBS, or IBS-D, have evidence of BAM, also known as bile acid diarrhea (BAD). Patients with idiopathic BAM with IBS-D have decreased production of the hormone FGF19. The aim of the 28-day, randomized, double-blind, placebo-controlled Phase 2 trial, which was conducted by researchers at the Mayo Clinic, was to examine the effects of aldafermin, an engineered variant of the human hormone FGF19, on biochemical endpoints and patient-reported outcomes, including bile acid synthesis, bile acid excretion and bowel function in patients with IBS-D and BAD.

Co-primary endpoints of the Phase 2 trial were change from baseline to day 28 in fasting serum 7αC4 and stool consistency, measured using the Bristol Stool Form Scale, or BSFS 1-7. 30 patients were included in the data analysis. Aldafermin-treated patients (n=15) demonstrated a statistically significant decrease in serum 7αC4 at days 14 and 28 compared to placebo (n=15) ($p<0.001$ vs placebo for both time points). Patients treated with aldafermin also had significantly decreased fecal total bile acids at days 14 and 28 compared to placebo ($p=0.002$ and $p<0.001$ respectively). There was numerically improved stool consistency in patients on aldafermin over time, particularly in week 4 of treatment, compared to placebo ($p=0.047$).

Aldafermin was generally well tolerated and had a safety and tolerability profile generally consistent with prior trials of the drug. Aldafermin-treated patients had a numerically greater increase in low-density lipoprotein cholesterol (LDL-C) from baseline compared to placebo group, consistent with previous study of the drug and as expected given aldafermin's mechanism of action as a potent inhibitor of the classical bile acid synthesis pathway. In previous studies of aldafermin, observed LDL-cholesterol increases were fully mitigated by concomitant statin use.

A copy of the presentation is available on NGM Bio's website at https://www.ngmbio.com/discovery-engine/publications/. A manuscript on the study has been accepted and published online in *Gastroenterology* (Gastroenterology 2023;S0016-5085(23)00621-2).

David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio, said, "The promising findings shared today, combined with the encouraging topline results from our ALPINE 4 trial in patients with cirrhotic NASH we announced last week, further our belief in the therapeutic potential of aldafermin. In totality, we have a substantial clinical data package to support our efforts to seek a partner for potential further development of aldafermin as we continue to focus our internal development efforts at NGM Bio on advancing our solid tumor oncology portfolio."

Aldafermin, discovered in-house and wholly owned by NGM Bio, has been dosed in over 800 patients and healthy volunteers across multiple liver and metabolic diseases, including more than 400 patients with non-alcoholic steatohepatitis (NASH), and has been generally well tolerated in clinical trials to date. Prior clinical trials have investigated a variety of applications of aldafermin including in patients with NASH with stage 2 or 3 liver fibrosis (F2/F3), stage 4 liver fibrosis (cirrhosis), primary sclerosing cholangitis (PSC), primary biliary cholangitis (PBC) and type 2 diabetes. In prior preclinical and clinical studies, aldafermin demonstrated the potential ability to reduce liver fat content, improve liver function, reverse fibrosis and resolve NASH by targeting multiple pathogenic pathways of liver disease.

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 four solid tumor oncology programs in clinical development. 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,” “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 therapeutic potential of NGM Bio’s product candidates, including aldafermin; NGM Bio’s continued pipeline development, including identification and engagement of third-party partners for potential future business development arrangements (“BD Arrangements”) to determine further development of aldafermin, and research and development and discovery engine output; the potential for aldafermin to treat patients with BAM and IBS-D as well as various disorders where dysregulated bile acid synthesis contributes to disease pathology; 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; NGM Bio’s reliance on its amended collaboration with Merck; NGM Bio’s ability to identify and engage third-party partners for BD Arrangements, if any, and its ability to attract such partners; 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 expected cash runway, including the risk that NGM Bio could utilize its available capital resources sooner than it currently expects and its need for additional capital; macroeconomic conditions (such as the impacts of the ongoing COVID-19 pandemic and the conflict between Russia and Ukraine, global economic slowdown, increased inflation, rising interest rates and recent and potential future bank failures); 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 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the United States Securities and Exchange Commission (“SEC”) on February 28, 2023 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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