Merck Exercises Option for NGM Bio's Investigational Insulin Sensitizer, NGM313, for the Treatment of NASH and Type 2 Diabetes

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KENILWORTH, N.J., and SOUTH SAN FRANCISCO, C.A. Jan. 3, 2019 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, and NGM Biopharmaceuticals, Inc. (NGM) today announced that Merck has exercised its option to license NGM313, an investigational monoclonal antibody agonist of the β-Klotho/FGFR1c receptor complex that is currently being evaluated for the treatment of nonalcoholic steatohepatitis (NASH) and type 2 diabetes. This is part of the companies' broad strategic collaboration to discover, develop and commercialize novel biologic therapeutics announced in 2015.

"We are pleased with the progress of this collaboration and look forward to future developments with NGM that build upon Merck's industry-leading position in metabolic diseases," said Dr. Joe Miletich, senior vice president, preclinical and early development, Merck Research Laboratories. "Merck is committed to advancing candidates with the potential to have a meaningful impact in the treatment of metabolic diseases, including NGM313 for NASH."

With the exercise of this one-time option, which was triggered by NGM's completion of a proof-of-concept clinical study of NGM313, Merck gains exclusive worldwide rights to develop, manufacture and commercialize NGM313, now renamed MK-3655, and related compounds. In connection with the option exercise, NGM received a $20 million payment from Merck. NGM retains an option, at the initiation of the first Phase 3 clinical trial for MK-3655, to participate in up to 50 percent of a global cost and revenue sharing arrangement for MK-3655. If NGM does not exercise its option, NGM is eligible for further payments associated with the progress of MK-3655 development, as well as commercial milestone payments and tiered royalties ranging from low double digit to mid-teen percentage rates on product sales.

"Merck's decision to exercise its option for NGM313 provides a strong endorsement of NGM's powerful drug discovery engine and our ability to translate our novel biologic insights in the clinic," said Dr. David Woodhouse, chief executive officer of NGM. "The Phase 1b data we presented last year demonstrate NGM313's potential as a potent, once-monthly insulin sensitizer for the treatment of both NASH and type 2 diabetes. We look forward to Merck's advancement of this program through clinical development to potentially address the substantial unmet medical need for a single treatment that addresses pathophysiological states common to both diseases."

In November 2018, NGM presented positive findings from a Phase 1b proof-of-concept clinical trial of NGM313 in obese, insulin resistant subjects with nonalcoholic fatty liver disease (NAFLD) at AASLD's The Liver Meeting ® 2018. In the study, preliminary data indicated that a single dose of NGM313 resulted in a statistically significant reduction in liver fat content (LFC) and improvements in multiple metabolic parameters after five weeks. Based on these data, Merck intends to advance NGM313 into a Phase 2b study to evaluate the effect of NGM313 on liver histology and glucose control in NASH patients with or without diabetes.

About MK-3655 (NGM313)

MK-3655 (formerly known as NGM313) is a proprietary, investigational agonistic antibody that selectively activates the β-Klotho/FGFR1c receptor complex. NGM313 binds to a unique epitope of β-Klotho, resulting in the selective activation of FGFR1c and signaling through one of the metabolic pathways utilized by FGF21-based ligand therapies. It does not trigger signaling through other FGF receptors, such as FGFR2c, FGFR3c or FGFR4. In Phase 1 studies, NGM313 has demonstrated potential as a once-monthly injectable insulin sensitizer.

Type 2 Diabetes, Insulin Resistance and NASH

Insulin resistance has been implicated as a key condition leading to hepatic steatosis and, subsequently, NASH, a life-threatening form of liver disease. An estimated 65% of type 2 diabetes patients have NASH. The presence of type 2 diabetes is associated with worse liver disease and, in patients with NAFLD and NASH, type 2 diabetes is associated with more severe hepatic and adipose tissue insulin resistance, and more advanced liver steatosis, inflammation and fibrosis by liver histology. In addition, administration of insulin may increase steatosis, making the treatment of patients with type 2 diabetes and NASH challenging. The role of insulin resistance and hyperglycemia in the pathogenesis of NAFLD suggests that improving insulin sensitivity and normalizing glucose levels could prevent the development of NASH and progression of disease.

About Merck and NGM's Collaboration

In 2015, Merck and NGM entered into a broad multi-year strategic collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. In addition to a $94 million upfront payment and purchase of $106 million of NGM's preferred stock, Merck committed up to $250 million to fund NGM's research and development efforts under the initial five-year term of the collaboration, with the potential for additional funding if certain conditions are met. Merck has the option to extend the research agreement for two additional two-year terms.

The collaboration includes an exclusive worldwide license to NGM's growth differentiation factor 15, or GDF15, program. Merck has a one-time option to license all resulting collaboration programs following human proof-of-concept trials. Upon exercising such options, Merck will lead global product development and commercialization for the resulting products, if approved. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50 percent. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States.

NGM's fibroblast growth factor 19, or FGF19, program, including NGM282, is excluded from the agreement and remains wholly owned by NGM.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world – including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

About NGM Biopharmaceuticals, Inc.

NGM is a clinical stage biopharmaceutical company focused on developing novel therapeutics based on scientific understanding of key biological pathways underlying cardio-metabolic, liver, oncologic and ophthalmic diseases. The company leverages its biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that enable it to move rapidly into proof-of-concept studies and deliver potential first-in-class medicines to patients. NGM aspires to operate one of the most productive research and development engines in the biopharmaceutical industry, with multiple programs in clinical development. Visit http://www.ngmbio.com for more information.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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