Moderna and Generation Bio Announce Strategic Collaboration to Develop Non-Viral Genetic Medicines

March 23, 2023

Collaboration will extend the applications of each company's platform through discovery and development of novel lipid nanoparticles using Generation Bio's proprietary stealth cell-targeted lipid nanoparticle (ctLNP) delivery system

Moderna has acquired an option to license Generation Bio's ctLNP and closed-ended DNA (ceDNA) technology for two immune cell programs and two liver programs, with an additional option for a third immune cell or liver program

Moderna will fund all research and development activities under the collaboration

Generation Bio will receive a $40 million upfront cash payment, a pre-payment of research funding, plus a $36 million equity investment from Moderna, with the potential for additional milestones, fees, and royalties

CAMBRIDGE, Mass., March 23, 2023 (GLOBE NEWSWIRE) -- Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, and Generation Bio Co. (Nasdaq:GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, today announced that the two companies have entered into a strategic collaboration to combine Moderna's biological and technical expertise with core technologies of Generation Bio's non-viral genetic medicine platform. The collaboration aims to expand the application of each company's platform by developing novel nucleic acid therapeutics, including those capable of reaching immune cells, to accelerate their respective pipelines of non-viral genetic medicines.

"Moderna continues to invest in innovative technology to enable us to develop a breadth of transformative medicines for patients," said Rose Loughlin, Ph.D., Moderna's Senior Vice President for Research and Early Development. "Through this collaboration, which builds on Generation Bio's non-viral genetic medicines platform, we have the potential to target immune cells with diverse nucleic acid cargos and the liver for gene replacement. We are excited to have Generation Bio as our partner as we continue to broaden our therapeutic pipeline and extend the potential benefit of nucleic acid therapeutics to more patients."

"Non-viral DNA therapeutics may offer durable, redosable, titratable genetic medicines to patients suffering from rare and prevalent diseases on a global scale," said Phillip Samayoa, Ph.D., Chief Strategy Officer of Generation Bio. "This collaboration represents a foundational investment in our platform science, both deepening our pipeline of rare and prevalent liver disease programs beyond hemophilia A and accelerating our work to reach outside of the liver with nucleic acid therapies. We are thrilled to collaborate with Moderna to extend genetic medicines to new tissues and cell types through the joint development of novel targeting for our stealth ctLNPs to reach immune cells."

About the Collaboration

Under the terms of the agreement, Moderna may advance two immune cell programs, each of which may use a jointly developed ctLNP to deliver ceDNA. In addition, Moderna may advance two liver programs, each of which may use a liver-targeted ctLNP developed by Generation Bio to deliver ceDNA. Moderna retains an option to license a third program for either immune cells or the liver.

Generation Bio will receive a $40 million upfront cash payment and a $36 million equity investment issued at a premium over recent share prices. Moderna will fund all collaboration work, including a research pre-payment. Generation Bio is also eligible for future development, regulatory and commercial milestone payments, as well as royalties on global net sales of liver-targeted and immune cell-targeted products commercialized under the agreement. The agreement additionally provides Moderna with the right, subject to certain terms and conditions, to purchase additional shares of common stock in connection with a future equity financing by Generation Bio.

Further, Moderna and Generation Bio will both leverage collaboration research to continue to advance *in vivo* immune cell targeting as a new class of genetic medicines, with downstream economics on products utilizing such technology. Generation Bio is eligible to receive certain exclusivity fees as well as potential development and regulatory milestones and royalties on products that Moderna advances using ctLNP technology developed under the collaboration.

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past eight years. To learn more, visit www.modernatx.com.

Moderna Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the terms of the research collaboration between Moderna and Generation Bio to develop novel nucleic acid

therapeutics, including the potential to target immune cells with diverse nucleic acid cargos and the liver for gene replacement; the targets to be developed under the collaboration; the funding to be paid by Moderna upon initiation of the collaboration and upon reaching certain milestones; and Moderna's $36 million equity investment in Generation Bio. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others, those risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC), and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this press release.

About Generation Bio

Generation Bio is innovating genetic medicines to provide durable, redosable treatments for people living with rare and prevalent diseases. The company's non-viral genetic medicine platform incorporates a novel DNA construct called closed-ended DNA, or ceDNA; a unique cell-targeted lipid nanoparticle delivery system, or ctLNP; and a highly scalable capsid-free manufacturing process that uses proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. This approach is designed to enable multi-year durability from a single dose, to deliver large genetic payloads, including multiple genes, to specific tissues and cell types, and to allow titration and redosing to adjust or extend expression levels in each patient. RES has the potential to expand Generation Bio's manufacturing scale to hundreds of millions of doses to support its mission to extend the reach of genetic medicine to more people, living with more diseases, around the world.

For more information, please visit www.generationbio.com.

Generation Bio Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the company, including statements about our strategic plans or objectives, our technology platform, our research and clinical development plans, and the potential benefits and results that may be achieved through the collaboration with Moderna and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: that the anticipated benefits and potential of Generation Bio's collaboration with Moderna may not be achieved on the anticipated timeline, or at all; that data may not support further development of the therapies subject to the collaboration due to safety, efficacy, or other reasons; uncertainties inherent in the identification and development of product candidates, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials and clinical development of the company's product candidates; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; whether results from earlier preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties regarding the RES manufacturing process; uncertainties regarding the company's ability to assign or sublease its manufacturing property; expectations for regulatory approvals to conduct trials or to market products; challenges in the manufacture of genetic medicine products; whether the company's cash resources are sufficient to fund the company's operating expenses and capital expenditure requirements for the period anticipated; the ongoing impact of the COVID-19 pandemic on the company's business and operations; expectations for regulatory approvals to conduct trials or to market products; as well as the other risks and uncertainties set forth in the "Risk Factors" section of our most recent annual report on Form 10-K, which is on file with the Securities and Exchange Commission, and in subsequent filings the company may make with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date on which they were made.

Moderna Contacts

Media:
Mary Beth Woodin
Senior Director, R&D Communications
MaryBeth.Woodin@modernatx.com
617-899-3991

Investors:
Lavina Talukdar
Senior Vice President & Head of Investor Relations
Lavina.Talukdar@modernatx.com
617-209-5834

Generation Bio Contact

Investors and Media
Maren Killackey
Generation Bio
mkillackey@generationbio.com
857-371-4638

SOURCE: Moderna, Inc.