Generation Bio Announces Plan to Scale Next-Generation Rapid Enzymatic Manufacturing Process Across Portfolio and Provides Pipeline Update

July 14, 2021

Company to transition all portfolio programs to rapid enzymatic synthesis (RES), enabling improved quality, scale and speed of closed-ended DNA manufacturing

Lease agreement signed to build an in-house RES manufacturing facility providing cGMP capacity for and internal control over clinical and initial commercial supply

IND submission for hemophilia A now planned for 2023; factor VIII expression data with RES material in non-human primates expected year-end 2021

CAMBRIDGE, Mass., July 14, 2021 (GLOBE NEWSWIRE) -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, announced today that it plans to deploy next-generation rapid enzymatic synthesis (RES) for manufacturing of its closed-ended DNA (ceDNA) constructs across all portfolio programs.

RES is a cell-free process that has the following advantages over cell-based manufacturing:

- **Quality**: Consistently yields highly pure ceDNA and reduces the variability inherent in cell-based manufacturing, which may have important regulatory and clinical benefits for Generation Bio's entire pipeline, including its lead hemophilia A program;
- **Scale**: Potential to expand ceDNA manufacturing scale to hundreds of millions of doses, supporting the company's intention to develop programs for prevalent diseases;
- **Speed**: Shortens the ceDNA production cycle from 28 days to one day, which will accelerate preclinical research and development across the company's portfolio.

The company has signed a lease agreement to build out a state-of-the-art cGMP (current good manufacturing practice) facility of approximately 104,000 square feet in Waltham, Mass. to scale RES for clinical and initial commercial supply. The facility is expected to be operational in 2023, enabling an Investigational New Drug (IND) application and clinical development for the company's lead hemophilia A program. The company is using existing infrastructure for RES production of research material.

"We are proud of our pioneering work with our ceDNA construct and cell-targeted lipid nanoparticle delivery system, and we are bringing that same level of innovation to manufacturing with RES. RES represents a step change in the quality, scale and speed of ceDNA production, and with our new manufacturing facility we maintain strong internal quality control while achieving scale and breadth to match the promise of our platform," said Geoff McDonough, M.D., chief executive officer at Generation Bio. "We believe the benefits of RES merit adjusting the timing of the IND submission for our hemophilia A program, and we expect the shift to RES to accelerate overall development timelines across the rest of our pipeline."

Generation Bio anticipates incurring net lease costs of $104 million over a 12-year period and investing up to $45 million in the new manufacturing facility over the next two years. The company plans to continue partnering with contract manufacturing organizations during and after construction to ensure redundancy and secure additional ceDNA supply. Expenditures on the new facility are not expected to impact Generation Bio's cash runway, which is sufficient to fund key milestones into 2024.

As Generation Bio transitions to RES, it expects to update its program development strategy and timelines across its pipeline. Generation Bio is currently advancing its liver-directed, cell-targeted lipid nanoparticle delivery system with RES for the lead hemophilia A program. The company expects to report factor VIII expression data using RES-produced drug product in non-human primates by year-end.

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 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 its proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. The platform is designed to enable multi-year durability from a single dose, to deliver large genetic payloads, including multiple genes, to specific tissues, 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 their 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.

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 platforms, our research and clinical development plans, the expected timing of the submission of IND applications and preclinical data, our manufacturing plans, our expectations regarding our new facility 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: 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 preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties regarding the timing and ability to complete the build-out of the Company's manufacturing facility and regarding the new manufacturing process; expectations regarding the timing of submission of IND applications; 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, including the funding of the new manufacturing facility; the impact of the COVID-19 pandemic on the company's business and operations; 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 and quarterly report on Form 10-Q, which are 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.

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