Generation Bio Announces Update to Its GMP Manufacturing Strategy

June 21, 2022

Company projects smaller GMP manufacturing footprint, enabled by further process development of rapid enzymatic synthesis of ceDNA at scale

Company will seek to sublease its planned GMP facility, and will adopt a more capital efficient, modular, and flexible manufacturing approach

Capital reallocated from facility buildout expected to extend cash runway into 2025

CAMBRIDGE, Mass., June 21, 2022 (GLOBE NEWSWIRE) -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, announced that it is updating its Good Manufacturing Process (GMP) manufacturing strategy to integrate efficiencies enabled by improvements to its proprietary rapid enzymatic synthesis (RES) process for the production of closed-ended DNA (ceDNA).

RES is a cell-free process that delivers three key benefits compared to biologics-based DNA manufacturing approaches: consistent yields of highly pure ceDNA, potential to scale to hundreds of millions of doses, and short production cycles. In July 2021, Generation Bio announced plans to deploy RES for ceDNA across all of its portfolio programs and had entered into a lease agreement to build out a GMP facility in order to scale RES for clinical and initial commercial supply. Through further process development of RES, the company has achieved a significant increase in scale while maintaining high productivity and ceDNA purity, and now projects underutilization of the planned GMP facility. The company will seek to sublease this facility and intends to execute an alternative GMP approach that retains control over personnel, quality, infrastructure and process know-how.

"The productivity, yield and short cycle time of our RES process at scale is expected to allow us to supply our portfolio through the next 10 years with a much smaller, flexible manufacturing footprint," said Antoinette Paone, chief operating officer of Generation Bio. "Since we anticipate no impact to timelines with this shift, we believe it is prudent to pursue a more operationally and financially efficient GMP manufacturing strategy."

By opting not to continue with the facility buildout, the company estimates an extension of its cash runway into 2025. The change in manufacturing strategy is not expected to affect production of ceDNA for Generation Bio's ongoing research on its liver, retina and vaccine programs.

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. The platform is designed to enable multi-year durability from a single dose, to deliver large genetic payloads, including multiple genes, to specific 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.

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 manufacturing plans, our cash resources, our technology platform, including our RES technology, our research and clinical development plans, applications and preclinical data 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 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 sublease its manufacturing facility; whether the changes to the company's manufacturing strategy reported in this release will achieve the anticipated savings; 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 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.

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