Sio Gene Therapies Announces Successful Manufacture of Three GMP Batches of AXO-Lenti-PD Gene Therapy for Parkinson's Disease

November 11, 2021

- Completed three successful GMP campaigns using suspension-based manufacturing process
- All batches achieved target titers and have successfully completed fill and finish
- Qualified Person (QP) certification of at least one batch of clinical trial material on-track for Q4 2021
- Obtained scientific advice from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. regarding continued clinical development
- Expect to provide program update in Q1 2022

NEW YORK and DURHAM, N.C., Nov. 11, 2021 (GLOBE NEWSWIRE) -- Sio Gene Therapies Inc. (NASDAQ: SIOX), a clinical-stage company focused on developing gene therapies to radically transform the lives of patients with neurodegenerative diseases, today provided a manufacturing and regulatory update for AXO-Lenti-PD, its clinical-stage gene therapy for Parkinson's disease.

"Today's announcement is the culmination of several months of effort by the Sio and Oxford BioMedica teams focused on the development of a reliable, suspension-based manufacturing process to enable scale-up of production and advancement of the AXO-Lenti-PD program," said Pavan Cheruvu, M.D., Chief Executive Officer of Sio Gene Therapies. "With the successful manufacture of three batches, all of which achieved the target titer and have completed fill and finish, we now have a process that has generated sufficient clinical trial material for future clinical development. We believe these data, coupled with scientific advice from the MHRA, help clarify the path forward and collectively represent an inflection point for the AXO-Lenti-PD program."

Key Highlights

- Three GMP batches have successfully completed fill and finish, achieving target titers using the updated suspension-based process
- Company is on-track to complete final testing of these three batches to support certification of at least one batch for use as clinical trial material by a Qualified Person in Q4 2021
- Additionally, the Company successfully completed a scientific advice meeting with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. regarding the AXO-Lenti-PD clinical development program. The MHRA provided guidance on the:
    1. Appropriate development pathway for completion of the Phase 1 dose-ranging study
    2. Acceptability of a comparability protocol between the prior adherent and new suspension manufacturing process
    3. New device administration system to support bilateral simultaneous infusions
- Expect to provide a program update in Q1 2022

About Sio Gene Therapies

Sio Gene Therapies combines cutting-edge science with bold imagination to develop genetic medicines that aim to radically improve the lives of patients. Our current pipeline of clinical-stage candidates includes the first potentially curative AAV-based gene therapies for GM1 gangliosidosis and Tay-Sachs/Sandhoff diseases, which are rare and uniformly fatal pediatric conditions caused by single gene deficiencies. We are also expanding the reach of gene therapy to highly prevalent conditions such as Parkinson's disease, which affects millions of patients globally. Led by an experienced team of gene therapy development experts, and supported by collaborations with premier academic, industry and patient advocacy organizations, Sio is focused on accelerating its candidates through clinical trials to liberate patients with debilitating diseases through the transformational power of gene therapies. For more information, visit www.siogtx.com.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "believe," "expect," "estimate," "may" and other similar expressions are intended to identify forward-looking statements. For example, all statements Sio makes regarding costs associated with its operating activities, funding requirements and/or runway to meet its upcoming clinical milestones, and timing and outcome of its upcoming clinical and manufacturing milestones are forward-looking. All forward-looking statements are based on estimates and assumptions by Sio's management that, although Sio believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Sio expected. Such risks and uncertainties include, among others, the impact of the Covid-19 pandemic on our operations; the actual funds and/or runway required for our clinical and product development activities and anticipated upcoming milestones; actual costs related to our clinical and product development activities and our need to access additional capital resources prior to achieving any upcoming milestones; the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the occurrence of adverse safety events during our current and future trials; the development of a suspension-based manufacturing process for AXO-Lenti-PD; the scaling up of manufacturing; the outcome of interactions with regulatory agencies and expectations for regulatory submissions and approvals; the continued development of our gene therapy product candidates and platforms; Sio's scientific approach and general development progress; and the availability or commercial potential of

Sio's product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Sio's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 12, 2021, as updated by its subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Sio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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