AGTC Receives Positive Type C Meeting Feedback from the FDA for the Company's Design and Operating Procedures of its Planned cGMP Manufacturing Facility

July 26, 2022

— FDA feedback marks a key milestone in the construction of the facility expected to support AGTC's pipeline, including the late-stage development and potential commercialization of AGTC's X-Linked Retinitis Pigmentosa (XLRP) and Achromatopsia B3 (ACHMB3) programs —

GAINESVILLE, Fla. and CAMBRIDGE, Mass., July 26, 2022 (GLOBE NEWSWIRE) -- Applied Genetic Technologies Corporation (Nasdaq: AGTC), a clinical-stage biotechnology company focused on the development and potential commercialization of adeno-associated virus (AAV)-based gene therapies for the treatment of rare and debilitating diseases with an initial focus on inherited retinal diseases, today announced that the U.S. Food and Drug Administration (FDA) provided favorable feedback on the Current Good Manufacturing Practice (cGMP) design of AGTC's manufacturing facility. In its feedback from a recent Type C meeting, the FDA concurred the facility design and proposed operating procedures are appropriate to support the cGMP manufacture of recombinant AAV drug substance.

In May 2022, AGTC announced that it had completed construction of the manufacturing facility's exterior structure and the FDA's feedback on the interior design of the facility helps assure the potential successful completion of next phase of construction. Initial operations at the facility are expected to begin in 4Q 2022 with GMP capabilities expected to be finalized in 1Q 2023.

"With the FDA's feedback, we are pleased to be on-track with the build out of our cGMP manufacturing facility, which is crucial in supporting the late-stage clinical development and potential commercialization of our lead XLRP and ACHMB3 programs," said Eduardo Jacobo, AGTC's Senior Vice President, GMP Manufacturing. "The on-going challenges and costs associated with external vendors underscore the value of developing a manufacturing facility specifically designed and prioritized to meet the needs and timelines for the development of our drug candidates, including AGTC-501 for XLRP, which we recently reported positive three-month interim data. As we continue to advance development of this promising candidate, our new facility will play a crucial role in its commercialization should it receive FDA approval. We expect the facility will also play an important role in support of our promising pipeline of additional clinical and pre-clinical programs."

In May 2022, AGTC announced positive three-month interim results from the Skyline Phase 2 expansion trial of AGTC-501, demonstrating robust improvements in visual sensitivity, the trial's primary efficacy endpoint, in multiple patients three months after dosing, with a 62.5% response rate in dose group B and a 25% response rate in dose group A. This is well above the statistically significant 50% response rate the Vista Phase 2/3 trial for AGTC-501 is powered to detect.

About AGTC

AGTC is a clinical-stage biotechnology company developing genetic therapies for people with rare and debilitating ophthalmic, otologic and central nervous system (CNS) diseases. AGTC is designing and constructing critical gene therapy elements and bringing them together to develop customized therapies with the potential to address unmet patient needs. AGTC's most advanced clinical programs in XLRP and ACHM CNGB3 leverage its technology platform to potentially improve vision for patients with inherited retinal diseases. Its preclinical programs build on the AGTC's AAV manufacturing technology and scientific expertise. AGTC is advancing multiple pipeline candidates to address substantial unmet clinical needs in optogenetics, otology and CNS disorders, and has entered into strategic collaborations with companies including Bionic Sight, Inc., an innovator in the emerging field of optogenetics and retinal coding, and Otonomy, Inc., a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology.

Forward-Looking Statements

This release contains forward-looking statements that reflect AGTC's plans, estimates, assumptions and beliefs, including statements about the expected timing for completion of the manufacturing facility and the potential for the new manufacturing facility to support the development and commercialization of AGTC's pipeline programs, the potential of the AGTC's gene therapy platform and the strength of its XLRP and ACHM B3 clinical programs, the potential of AGTC-501 as a treatment for XLRP, the ability to use the interim Skyline clinical trial results as a predictor of the success of the final Skyline and Vista clinical trial results and whether these results will support future regulatory filings for AGTC-501. Forward-looking statements include information concerning possible or assumed future results of operations, financial guidance, business strategies and operations, preclinical and clinical product development and regulatory progress and the expected timing thereof, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions and the negatives of those terms. Actual results could differ materially from those discussed in the forward-looking statements, due to a number of important factors. Risks and uncertainties that may cause actual results to differ materially include, among others: gene therapy is still novel with only a few approved treatments so far; AGTC cannot predict when or if it will obtain regulatory approval to commercialize a product candidate or receive reasonable reimbursement; uncertainty inherent in clinical trials and the regulatory review process; risks and uncertainties associated with drug development and commercialization; risks and uncertainties relating to the construction and operation of a cGMP manufacturing facility; risks and uncertainties related to funding sources for our development programs and manufacturing facility; the direct and indirect impacts of the ongoing COVID-19 pandemic on the Company's business, results of operations, and financial condition; factors that could cause actual results to differ materially from those described in the forward-looking statements are set forth under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2019, as amended, filed with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent management's plans, estimates, assumptions and beliefs only as of the date of this release. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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