AGTC Announces Expansion of Manufacturing and Analytics Capabilities to Advance Commercialization of Gene Therapy Product Candidates

May 13, 2021

- Company plans to lease 21,000 square foot build-to-suit cGMP manufacturing facility adjacent to its Florida facility -

- Obtained additional $10 million in debt and maturity extension under an amended loan agreement with Hercules -

GAINESVILLE, Fla. and CAMBRIDGE, Mass., May 13, 2021 (GLOBE NEWSWIRE) -- Applied Genetic Technologies Corporation (Nasdaq: AGTC), a biotechnology company conducting human clinical trials of adeno-associated virus (AAV)-based gene therapies for the treatment of rare diseases, today announced that it has initiated plans to lease a build-to-suit 21,000 square foot current Good Manufacturing Practices (cGMP) manufacturing and quality control facility adjacent to its Florida facility to prepare for anticipated late-stage development of its X-Linked Retinitis Pigmentosa (XLRP) and Achromatopsia (ACHM) programs. Build-out of this cGMP facility, which is expected to be completed in the second half of 2022, is part of the Company's strategy to enable more rapid filing of a Biologics Licensing Application and commercial launch of its XLRP candidate upon potential United States Food and Drug Administration (FDA) approval. The cGMP facility is also expected to support more rapid advancement of the Company's product pipeline while providing supply chain redundancy and reducing manufacturing risk.

"This manufacturing build-out reinforces our commitment to the advancement of our XLRP candidate through a Phase 2/3 clinical trial and, if approved, eventual commercialization. We are taking steps to increase control over our cGMP manufacturing and analytical release to ensure that we can meet anticipated future demand for our current clinical candidates and our exciting pre-clinical opportunities," said Sue Washer, President and Chief Executive Officer of AGTC. "This state-of-the-art manufacturing facility will provide us with the flexibility to pursue additional indications that have large patient populations and/or require substantially higher doses to provide efficacy."

The Company presented new data from two studies related to improvements in the manufacturing process for its XLRP gene therapy candidate on May 11, 2021 at the American Society of Gene & Cell Therapy (ASGCT) 24th Annual Meeting, which was held virtually May 11-14, 2021. These improvements will support manufacturing and quality release for the Phase 2/3 Vista trial by our current manufacturing partners, and potential late-stage trials for ACHM as the Company works toward finalizing a commercial manufacturing process that could meet potential market demand.

On May 6, 2021, AGTC reported new data from its ongoing Phase 1/2 XLRP clinical trial that further support the best-in-class potential of its XLRP candidate. The updated data among patients who met the inclusion criteria for the Skyline and Vista trials show a 50% response rate in Groups 5 and 6 at month 12 based on improvements in visual sensitivity; a statistically significant difference with respect to visual acuity in treated compared with untreated eyes for patients in Groups 2, 4, 5 and 6 and month 12; and continued durability of response at month 24 in two of three Group 4 patients available for evaluation at the time point. The complete 12-month data will be presented at the American Academy of Ophthalmology annual meeting in November 2021 and the Company remains on track to report 3-month masked interim Skyline data in the fourth quarter of 2021, 12-month Skyline data in the third quarter of 2022, and 6-month masked interim Vista the fourth quarter of 2022.

"We are confident that our expanding body of data supports the unparalleled potential of our XLRP product candidate, and we are moving quickly to advance commercialization plans on multiple fronts," said David R. Knop, Ph.D., Vice President of Process Development at AGTC. "We have developed a robust, reproducible, scalable and highly productive AAV manufacturing process and associated analytics, which allows for a modest sized facility to fulfill supply requirements through commercialization."

The Company plans to support its cGMP manufacturing and quality control strategic investment through a combination of robust tenant improvement allowances and tiered rental rates during construction of the build-to-suite facility. Equally as important, on May 13, 2021, the Company amended its Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. (NYSE: HTGC). Under the amended Loan Agreement, a second term loan advance of $10.0 million was authorized and advanced to the Company. Additionally, the interest-only period and loan maturity date were extended to March 31, 2022 and April 1, 2024, respectively, and, in the event that the Company meets certain conditions, including achievement of performance milestones, the Company has the ability to further extend those dates. The Company also has the right, subject to the lenders' sole discretion, to receive additional term loan advances of up to $5.0 million prior to April 1, 2022 or, if certain conditions are satisfied, then prior to January 1, 2023. All other material terms of the Loan Agreement were unchanged.

"This additional funding from Hercules Capital will support AGTC's investment in internal manufacturing capabilities, while further advancing its clinical pipeline. We are pleased to be able to amend our current debt facility and provide the additional growth capital to support these efforts," said Bryan Jadot, Senior Managing Director and Life Sciences Group Head for Hercules.

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 a leader in designing and constructing all critical gene therapy elements and bringing them together to develop customized therapies that address real patient needs. AGTC's most advanced clinical programs leverage its best-in-class technology platform to potentially improve vision for patients with an inherited retinal disease. AGTC has active clinical trials in X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM CNGB3 and ACHM CNGA3). Its preclinical programs build on the Company's industry leading AAV manufacturing technology and scientific expertise. AGTC is advancing multiple important pipeline candidates to address substantial unmet clinical need in optogenetics, otology and CNS disorders. In recent years AGTC has entered into strategic partnerships with companies including Otonomy, Inc., a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, and Bionic Sight, LLC, an innovator in the emerging field of optogenetics and retinal coding.

Forward-Looking Statements

This release contains forward-looking statements that reflect AGTC's plans, estimates, assumptions and beliefs. Forward-looking statements include information about the Company's planned build-to-suit lease, the expected timing for the build out of the facility and its potential to support early-stage pipeline programs, 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: risks related to new construction; 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; 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, 2020 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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