AGTC Expands Leadership Team with Appointment of Key Regulatory Leader

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AGTC Appoints Regulatory Expert, Janet C. Rae, RAC, as SVP of Global Regulatory and Quality

GAINESVILLE, Fla. and CAMBRIDGE, Mass., May 26, 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 retinal diseases, today announced the appointment of Janet C. Rae, RAC, as Senior Vice President of Global Regulatory and Quality. The appointment of Ms. Rae, who will join AGTC on June 18, 2021, is an important step in the Company's strategy to prepare for anticipated late-stage development of its X-Linked Retinitis Pigmentosa (XLRP) and Achromatopsia (ACHM) programs. She will be instrumental in assuring regulatory compliance as the Company initiates its previously announced 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.

"We are thrilled to welcome Janet as another high-caliber member of AGTC's management team and expect that her extensive expertise will enable her to lead our global regulatory and quality groups and develop our long-term strategy effectively. Janet's arrival comes at an extremely exciting time for AGTC as we just announced positive data from our ongoing Phase 1/2 XLRP clinical trial and planned expansion of our manufacturing and analytics capabilities," said Sue Washer, President and CEO of AGTC. "As we prepare for multiple clinical milestones in XLRP and ACHM in 2021 and 2022, Janet's expertise in not only regulatory strategies but in gene therapy and rare diseases will be critical to our next steps."

Ms. Rae brings nearly 30 years of experience in the regulatory affairs industry across drug, biologic and gene therapy products with a specialization in orphan drugs and rare disease therapy development. Most recently, she served as Vice President, Head of Regulatory Affairs for Gene Therapy at Ultragenyx Pharmaceutical Inc., where she was accountable for the development and oversight of global regulatory strategies and related regulatory operations across the company's gene therapy portfolio of products. Prior to joining Ultragenyx, she held positions at Dimension Therapeutics, Shire, Bentley Pharmaceuticals and PAREXEL International.

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, including statements 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 and the anticipated late-stage development of its X-Linked Retinitis Pigmentosa (XLRP) and Achromatopsia (ACHM) programs. 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, potential growth opportunities, potential market opportunities, the effects of competition and the impact of the COVID-19 pandemic, including the impact on its ability to enroll patients. 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; the direct and indirect impacts of the ongoing COVID-19 pandemic on our 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 our most recent annual or quarterly report and in other reports we have 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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