



## **AGTC Announces Departure of Chief Medical Officer, Company on Track to Announce XLRP and ACHM Data in January 2020**

December 2, 2019

GAINESVILLE, Fla. and CAMBRIDGE, Mass., Dec. 02, 2019 (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 Theresa Heah, M.D., Chief Medical Officer, has resigned from the company to pursue other opportunities.

Given that the clinical results for the upcoming data releases are still being processed at external vendors and not yet available for internal review, Dr. Heah's resignation does not relate to any knowledge of pending results. Dr. Heah has agreed to stay with the company until the end of the year to support the up-coming data analysis.

In addition, Dr. Heah's departure does not affect the company's previously announced guidance on the timing of data reporting from its ongoing Phase 1/2 clinical trials in patients with X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM):

### **XLRP**

AGTC expects to report interim six-month data from the expansion group of its Phase 1/2 XLRP study in January 2020. The company also plans to present a comprehensive data set at its January 28, 2020 R&D Day that will include data on additional patients.

### **ACHM**

AGTC expects to report interim six-month data from the dose escalation group of both the achromatopsia B3 and A3 Phase 1/2 studies in January 2020. The company plans to present a comprehensive data set from the six-month dose escalation groups at the R&D Day, at which time the company also plans to provide clarity on forward guidance on the programs.

"We are on track to present data from our ongoing Phase 1/2 clinical programs in X-linked retinitis pigmentosa and both achromatopsia trials, and continue to advance discussions with the FDA such that we can finalize the design and initiate a pivotal trial in X-linked retinitis pigmentosa as planned in 2020," said Sue Washer, President and CEO of AGTC. "Our treatment candidates have the potential to dramatically improve visual function in patients with conditions where only palliative or no therapies exist today."

The Company is exploring options to fill the role of CMO. In the interim, Dr. Matt Feinsod, M.D., who currently serves as Executive Vice President of Global Strategy and Development, and Dr. Nnenna Ihekoromadu, M.D., who recently joined the company as VP Clinical Research and Medical Affairs, will continue to provide medical oversight for the XLRP and ACHM clinical programs.

### **Recent Highlights**

Recently, AGTC announced positive data from the ongoing Phase 1/2 trial in patients with X-linked retinitis pigmentosa (XLRP), demonstrating stabilization of decline in the peripheral vision, improvement in central vision, and a favorable safety profile. Based on its ongoing discussion with physicians and advocacy groups, the company expects these results will be highly meaningful to XLRP patients, who today have no treatment options that address the underlying cause of their disease. AGTC also announced positive data demonstrating biological activity in its ongoing Phase 1/2 trials in patients with achromatopsia (ACHM) due to mutations in the ACHM B3 or A3 genes.

### **About AGTC**

AGTC is a clinical-stage biotechnology company that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases. Its initial focus is in the field of ophthalmology, in which it has active clinical trials in X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM CNGB3 & ACHM CNGA3). In addition to its clinical trials, AGTC has preclinical programs in optogenetics, adrenoleukodystrophy (ALD), which is a disease of the central nervous system (CNS) and other CNS, ophthalmology and other indications. The optogenetics program is being developed in collaboration with Bionic Sight. The otology program is being developed in collaboration with Otonomy. AGTC has a significant intellectual property portfolio and extensive expertise in the design of gene therapy products including capsids, promoters and expression cassettes, as well as expertise in the formulation, manufacture and physical delivery of gene therapy products.

### **Forward-Looking Statements**

*This release contains forward-looking statements that reflect AGTC's plans, estimates, assumptions and beliefs. 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; 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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