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AGTC and SAFC Create Strategic Partnership to Provide Gene Therapy Manufacturing Services

GAINESVILLE, Fla. and CARLSBAD, Calif., June 24, 2014 (GLOBE NEWSWIRE) -- Applied Genetic Technologies Corporation (Nasdaq:AGTC), a clinical stage biotechnology company developing adeno-associated virus (AAV)-based gene therapies for the treatment of rare eye diseases, and SAFC Commercial (SAFC), the Sigma-Aldrich Corporation (Nasdaq:SIAL) business unit that manufactures specialty chemicals and biologics for commercial life science applications, today announced that they signed an agreement to have SAFC provide gene therapy manufacturing services to companies developing gene-based therapies. Under the terms of the agreement, the two companies will co-market AGTC's proprietary HAVE manufacturing method with SAFC's cGMP manufacturing capabilities. AGTC will assist clients in engineering AAV-based vectors and the associated helper viruses for HAVE-based manufacturing activities. SAFC will manufacture AAV vectors with the HAVE system to either support initial research or in accordance with cGMP requirements to support clinical trial development and eventual commercial production. Through this partnership, clients will also have access to bio-manufacturing testing services from BioReliance, SAFC's biologics and early-development services business.

"AGTC has established an effective and productive relationship with SAFC to manufacture AAV-based vectors for our own portfolio of gene-based product candidates for rare eye diseases," said Sue Washer, President and CEO of AGTC. "AAV vectors have broad potential in treating a variety of genetic diseases, but until recently, could not be manufactured at clinical and commercial scale in a cost-effective manner. Our proprietary HAVE system overcomes these difficulties. In partnering with SAFC, we can now make our AAV manufacturing platform available to academic and corporate organizations that are pursuing gene-based therapies. SAFC is an excellent partner for this endeavor because it is a leading biologics CMO, has substantial expertise with our HAVE system and is known for providing a high level of service to its contract manufacturing customers."

"SAFC is committed to providing our customers with high-quality and timely cGMP manufacturing services," said David M. Backer, Sr. Director & General Manager at SAFC. "AGTC's proprietary HAVE system for manufacturing AAV vectors is an excellent fit for our portfolio of services and is consistent with the level of quality and technical capabilities that our customers expect from us. We believe that partnering with AGTC to provide gene therapy manufacturing services is an effective way to make this important technology available to a broader audience, and may help to expedite the development of novel therapies."

AAV is a naturally occurring virus that has never been known to cause disease in humans. It is a small, simple virus with only two genes. Using AGTC's proprietary HAVE process, this simplicity facilitates the engineering of AAV vectors that deliver DNA sequences that can correct the underlying cause of genetic diseases. AGTC's proprietary manufacturing method uses a recombinant herpes simplex virus (HSV) complementation system to produce high-titer, high potency AAV vector stocks that are purified via completely scalable methods. AGTC has tested AAV vectors produced with this system in clinical trials involving more than 100 patients in several disease indications.

Financial terms of the agreement were not disclosed.

About AGTC

AGTC is a clinical-stage biotechnology company that uses its proprietary gene therapy platform to develop products designed to transform the lives of patients with severe inherited orphan diseases in ophthalmology. AGTC's lead product candidates, which are each in the preclinical stage, focus on X-linked retinoschisis, achromatopsia and X-linked retinitis pigmentosa, which are rare diseases of the eye, caused by mutations in single genes, that significantly affect visual function and currently lack effective medical treatments. For additional information visit www.agtc.com

About SAFC

SAFC Commercial, the custom manufacturing and services business unit of Sigma-Aldrich Corporation, is recognized as a top 10 global specialty chemicals and biologics supplier. As a trusted manufacturer for the life science and high-technology industries, SAFC works closely with customers to resolve development challenges and accelerate the product pipeline using its global "Centers of Excellence" and dedicated manufacturing facilities. Its rich portfolio includes high-purity inorganic materials for high-technology applications, critical raw materials and extensive biologics safety testing services for biopharmaceutical

manufacturing, and complex, high-potent APIs and key intermediates for pharmaceutical manufacturing. For more information, visit <http://www.sigmaaldrich.com/safc.html>.

About Sigma-Aldrich

Sigma-Aldrich, a leading life science and high-technology company focused on enhancing human health and safety, manufactures and distributes 230,000 chemicals, biochemicals and other essential products to more than 1.4 million customers globally in research and applied labs as well as in industrial and commercial markets. With three distinct business units - Research, Applied and SAFC Commercial - Sigma-Aldrich is committed to enabling science to improve the quality of life. The Company operates in 37 countries, has more than 9,000 employees worldwide and had sales of \$2.7 billion in 2013. For more information about Sigma-Aldrich, please visit its website at www.sigma-aldrich.com.

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Forward Looking Statements

This press release contains forward-looking statements. Such statements reflect the plans, estimates, assumptions and beliefs of AGTC and SAFC and are subject to risks and uncertainties. Actual results could differ materially from those stated or implied in this press release, including but not limited to lower than expected market acceptance of the use of AAV vectors or AGTC's HAVE manufacturing process or challenges in utilizing such manufacturing processes to other companies' product candidates. Forward-looking statements include information concerning possible or assumed future results of operations, business strategies and operations, preclinical and clinical product development and regulatory progress, financing plans, 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. Given the risks and uncertainties associated with such statements, you should not place undue reliance on these forward-looking statements. For further discussion of factors that could cause actual results to differ from those discussed in the forward-looking statements, please refer to the risk factors discussed in each of AGTC's and SIAL's filings with the Securities and Exchange Commission. Also, forward-looking statements represent management's plans, estimates, assumptions and beliefs only as of the date of this press release. Except as required by law, neither AGTC nor SAFC undertakes any obligation to update these forward-looking statements.

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