Charles River to Perform Plasmid Manufacturing for AAVantgarde

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Critical starting material manufacture for therapeutic targeting high unmet need ophthalmology indication

WILMINGTON, Mass.--(BUSINESS WIRE)--Jul. 8, 2024-- Charles River Laboratories International, Inc. (NYSE: CRL) and AAVantgarde today announced a contract development and manufacturing organization (CDMO) agreement to produce Good Manufacturing Practice- (GMP) plasmid DNA. AAVantgarde, a clinical-stage biotechnology company with two proprietary adeno-associated viral (AAV) vector platforms for large gene delivery and developing products to treat inherited retinal diseases, will leverage Charles River's expertise in manufacturing GMP plasmid DNA.

AAVantgarde has two proprietary AAV-based large gene delivery platforms, both of which aim to enable efficient delivery of large genes to tissue and cells *in vivo*. Within this collaboration, Charles River will develop the plasmid DNA for AAVantgarde's Stargardt's disease program (AAVB-039), using their AAV-intein platform, which has demonstrated a very efficient recombination to deliver therapeutically meaningful protein levels.

Stargardt's is the most prevalent inherited macular dystrophy and is an autosomal recessive genetic disorder due to mutations in the ABCA4 gene characterized by progressive loss of central vision starting from childhood or adolescence, leading to profound vision loss. It is the most common form of inherited juvenile macular degeneration representing a very high unmet need as there are currently no therapies available for a disease that affects approximately 1:6,500 people.

Plasmid DNA Manufacturing Services

In recent years, Charles River has significantly broadened its cell and gene therapy portfolio to simplify complex supply chains and meet the growing demand for plasmid DNA, viral vector, and cell therapy services. Combined with Charles River's legacy testing capabilities, developers can leverage a comprehensive "concept to cure" advanced therapies solution.

Through this collaboration, AAVantgarde will have access to Charles River's GMP plasmid DNA CDMO center of excellence based in Keele, United Kingdom, which will lead the collaboration and additional evaluation of off-the-shelf Rep/Cap and pHelper plasmid products in addition to GMP manufacturing services to support therapeutic development.

To learn more about Charles River's CDMO product and service portfolio, and gain real-world insights from a development, manufacturing, and testing perspective, available on demand is an expert roundtable hosted by Human Gene Therapy, Streamlining Cell and Gene Therapy Scalability: Progress Towards a Gold Standard, featuring panelists James Cody, PhD Associate Director, Technical Evaluations, Charles River and Lisa Kirkwood, Associate Director, Analytical, AAVantgarde: https://bit.ly/4b7aN3A

Approved Quotes

- "Charles River is thrilled to produce GMP plasmid DNA to help advance AAVantgarde's platform for the treatment of Stargardt's disease – a condition in which there is high unmet need. Our team brings more than two decades of CDMO expertise, and we look forward to leveraging these capabilities to make a difference for patients." – Kerstin Dolph, Corporate Senior Vice President, Global Manufacturing, Charles River
- "By collaborating with Charles River, we are one step closer to beginning clinical trials to ensure our therapeutic product for Stargardt's Disease is safe and efficacious for patients. We trust the team's decades of success developing, producing, and reliably delivering plasmid DNA and look forward to expanding treatment options for this patient population." – Nina Kotsopoulou, PhD, Chief Technical Officer, AAVantgarde

About Charles River

Charles River provides essential products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions around the globe accelerate their research and drug development efforts. Our dedicated employees are focused on providing clients with exactly what they need to improve and expedite the discovery, early-stage development and safe manufacture of new therapies for the patients who need them. To learn more about our unique portfolio and breadth of services, visit www.criver.com.

About AAVantgarde

AAVantgarde is a clinical-stage, Italian headquartered, international biotechnology company that has developed two proprietary adeno-associated viral (AAV) vector platforms to address the gene therapy cargo capacity limitations of AAV vectors. The AAVantgarde platforms could be used to deliver large genes to ocular and non-ocular tissues. Co-founded by Professor Alberto Auricchio at TIGEM (Telethon Institute of Genetics and Medicine) in Naples, Italy, and Telethon Foundation, AAVantgarde will initially validate the platforms in the clinic in two inherited retinal diseases with clear unmet need. For more information, please visit: www.aavantgarde.com.

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