Charles River Launches nAAVigation Vector Platform to Accelerate Gene Therapy Programs

October 10, 2022 at 8:00 AM EDT

- *Platform has the capability to reduce time from process development to GMP by 55 percent and deliver a drug product in fewer than 8 months*
- *nAAVigation platform will be launched at the Cell & Gene Meeting on the Mesa*

WILMINGTON, Mass.--(BUSINESS WIRE)--Oct. 10, 2022-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced the launch of its nAAVigation™ Vector Platform (nAAVigation). Leveraging decades of Adeno-Associated Virus (AAV) vector contract development and manufacturing (CDMO) experience and biologics testing expertise, Charles River has established a platform which streamlines the pathway to GMP AAV vector manufacturing without the need for significant process development. The nAAVigation platform has the capability to reduce a program's timeline to GMP for viral vector gene therapy developers by 55 percent, translating to fewer than eight (8) months compared to traditional manufacturing workflows.

Charles River's nAAVigation approach is based on a proprietary high-productivity HEK293 suspension cell line, which is amenable to clients' scale-up and serotype needs. nAAVigation utilizes an optimized single-use upstream approach coupled with robust downstream purification processes, enabling client AAV programs to scale up to 500L in suspension. The nAAVigation platform accelerates time to clinic by leveraging established development processes, on-hand materials, templated documents, and 100 percent qualified, in-house analytics.

Meeting on the Mesa

Charles River will launch the nAAVigation platform approach and will highlight its benefits during a reception on October 12, during Cell and Gene Meeting on the Mesa, in Carlsbad, CA.

Ramin Baghirzade, PhD, Senior Director, Global Head Commercial, Gene Therapy CDMO Services will present at the Reception in the Command Post Meeting Room:

- nAAVigation™ Vector Platform: Accelerating Your AAV Pathway to GMP and Clinic - Wednesday, October 12, 5:00pm – 8:00 pm PST

In addition, Nicholas Ostrout, PhD, Senior Advisor, Cell and Gene Therapy Corporate Strategy, will present in Aviara Salon A:

- The Future of CDMO Networks in Cell and Gene Therapy - Wednesday, October 12, 7:45am – 8:45am PST

Daniel Smith, PhD, Executive Director, Global Cell and Gene Therapy Portfolio will present in UBC Ballroom:

- New Business Models for Manufacturing Investment - Wednesday, October 12, 3:15pm – 4:15pm PST

Join Charles River for three days of partnering and industry updates on clinical trial design, alternative payment models, scale-up and supply chain platforms for advanced therapies, and more.

Viral Vector CDMO Services

With over 20 years of viral vector CDMO expertise and a validated platform process with a proven track record, Charles River has standardized protocols for cell culture, transfection, and downstream purification. These high-yield, optimized methods increase speed to clinical manufacturing by reducing process development time and costs while ensuring the highest quality production.

nAAVigation builds on Charles River's industry-leading viral vector CDMO capabilities with established processes for AAV production and purification, and testing expertise.

Expanding its comprehensive cell and gene therapy portfolio to span viral vector, plasmid DNA, and cell therapy production, through the acquisitions of Vigene Biosciences, Cobra Biologics, and Cognate Bioservices in 2021, the Company offers end-to-end support and supply chain simplification for advanced therapy (ATMP) developers.

Approved Quotes

- "The launch of the nAAVigation Vector Platform process is the latest in a series of portfolio enhancements aimed at supporting our cell and gene therapy clients from early target identification through clinical-stage manufacturing. By increasing speed and efficiency for viral vector production, nAAVigation will help accomplish our ultimate goal of delivering safe, effective therapies to patients faster." – Kerstin Dolph, Corporate Senior Vice President, Biologics Solutions, Charles River
- "The significant turnaround time reduction for viral vector therapy developers utilizing nAAVigation combined with Charles River's established development process, standard, on-hand materials, templated documents, and in-house analytics will enhance our clients' experiences."– Professor Daniel Smith, Executive Director Global Cell and Gene Therapy Portfolio,

Charles River

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.

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