Charles River Launches Rep/Cap Plasmids to Streamline Adeno-Associated Viral Vector Manufacturing

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Off-the-shelf Rep/Cap simplifies gene therapy supply chains with immediate availability

WILMINGTON, Mass.--(BUSINESS WIRE)--Jan. 16, 2024-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced the launch of its off-the-shelf Rep/Cap plasmid offering, designed to streamline adeno-associated virus (AAV)-based gene therapy programs.

Following the previously announced launch of its lentiviral packaging and AAV Helper plasmid products, the addition of AAV Rep/Cap (RC2, 5, 6, 8, 9) supplements a comprehensive range of contract development and manufacturing organization (CDMO) products and services, reducing manufacturing effort by up to 66%. The ready-to-use plasmid products are produced and released according to batch production records, with CMC guidance and a Certificate of Analysis (COA) to support Investigational New Drug (IND) and Clinical Trial Application (CTA) filing.

Using standard off-the-shelf plasmids, such as Helper and Rep/Cap plasmid required for AAV production, gene therapy developers leverage the advantages of being immediately available, reducing development costs, risks, and timelines, subsequently simplifying supply chains. Charles River's Rep/Cap has been used successfully to support the production of a range of AAV serotypes carrying various therapeutic transgenes at multiple development and GMP production scales.

Advanced Therapies Week Launch

Charles River will officially launch the off-the-shelf Rep/Cap plasmid offering during Advanced Therapies Week, January 16-19, at the Miami Beach Convention Center.

Ramin Baghirzade, PhD, Senior Director, Global Head Commercial, Gene Therapy CDMO Services, will present: *How to Expedite your Gene Therapy Program: Platform Manufacturing Approaches*. Join Dr. Baghirzade in the Gene Therapy Manufacturing Track as part of the Regulatory Alignment for Gene Therapy Manufacturing session to learn how to:

- Ensure alignment with phase-appropriate plasmid DNA, AAV, and lentiviral vector (LVV) manufacturing best practices
- Adopt an established platform approach for speed and predictability
- Jump-start production with off-the-shelf products

Matthew Hewitt, B.A. PhD, Vice President, Technical Officer CGT & Biologics, and a wealth of expert speakers will explore: *The Future of Cell and Gene Therapy Manufacturing, Development, and Commercialization*.

- Development of Cell and Gene Therapies: Preclinical CRO perspective
- Delivering Next Generation CGT Manufacturing Solutions
- A Decentralized CDMO Manufacturing Strategy for Future Readiness
- Market Access and Reimbursements

Plasmid DNA and Viral Vector CDMO Services

The addition of Rep/Cap plasmids completes a comprehensive range of off-the-shelf plasmid products to support AAV and LVV production and follows the launch of the eXpDNA™ plasmid, nAAVigation™ AAV, and Lentivation™ lentiviral vector manufacturing platforms, established over decades o plasmid DNA and viral vector CDMO track records to expedite turnaround times.

Charles River has significantly broadened its cell and gene therapy portfolio with several acquisitions and capacity expansions to simplify complex supply chains and meet the growing global demand for plasmid DNA, viral vector, and cell therapy services. Combined with the Company's legacy testing services, Charles River offers an industry-leading "concept-to-cure" solution for advanced therapies, helping developers to navigate the path to clinic and beyond.

For more information, register for Charles River's upcoming BioInsights webinar on February 21, 2024, hosted by Andrew Frazer, PhD, Associate Director, Scientific Solutions, Gene Therapy CDMO Services, to explore Expediting Development and Manufacture of Advanced Therapies: Critical Starting Materials Case Study: https://bit.ly/3tPnakC

Approved Quotes

- "The launch of Charles River's off-the-shelf Rep/Cap offering is the latest in a series of portfolio enhancements designed to streamline adeno-associated virus (AAV)-based gene therapy programs. The reduction in production time and improved efficacy of the supply chain will help accomplish our ultimate goal of delivering safe, effective therapies to patients, faster." – Kerstin Dolph, Senior Vice President, Manufacturing, Charles River
- "Gene therapy clients leveraging the Rep/Cap offering, combined with Charles River's established CDMO capabilities and phase-appropriate approach, can expect reduced development costs, risks, and timelines while ensuring the highest quality product." - Andrew Frazer, PhD, Associate Director, Scientific Solutions, Gene Therapy CDMO Services, 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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Investor:
Todd Spencer
Corporate Vice President,
Investor Relations
781.222.6455
todd.spencer@crl.com

Media:
Amy Cianciaruso
Corporate Vice President,
Chief Communications Officer
781.222.6168
amy.cianciaruso@crl.com

Source: Charles River Laboratories International, Inc.