Charles River Launches CliniPrime Suite of GMP-Compliant Cellular Products

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This initial launch includes the CliniPrime Fresh Leukopak, supporting clinical trials and commercialization of advanced therapies

WILMINGTON, Mass.--(BUSINESS WIRE)--Jan. 16, 2023-- Charles River Laboratories International, Inc. (NYSE:CRL) today announced the launch of their new CliniPrime™ suite of Good Manufacturing Practice (GMP)-compliant cellular starting materials. CliniPrime products provide rapid access to starting materials for cell, and gene-modified cell therapies with a standardized production process for high-quality GMP-compliant products. All CliniPrime products meet the essential regulatory guidelines for clinical trial development and the commercial manufacturing of advanced therapies.

The first CliniPrime product, the CliniPrime Fresh Leukopak, fulfills the industry need for ready access to cGMP-enabled, enriched leukocyte cellular starting materials. CliniPrime leverages Charles River's established production processes to provide advanced therapy programs a high-quality product offering to support both clinical trial development and commercialization, while reducing client resource investment and risk.

With the CliniPrime portfolio Charles River now offers two options for GMP-compliant cellular starting material. CliniPrime products provide a standardized production process while GMPrime™products enable clients to customize the production process of cellular starting material to meet specific needs for their program. Those two options for GMP-compliant starting material are also complemented by the HemaPrime portfolio of research use only (RUO) cellular products that include fresh leukopaks and other cellular products.

Charles River has been a trusted provider of cell products and services for leading developers of cutting-edge cell therapies and basic research for more than 40 years through its acquisitions of HemaCare and Cellero (formerly Key Biologics and Astarte Biologics), now officially integrated as Charles River Cell Solutions. Charles River's donor centers, known as HemaCare Donor Centers, are available coast-to-coast with locations in Northridge, CA, Bothell, WA, Memphis, TN and Lowell, MA.

An Advanced Donation Process

HemaCare Donor Centers are FDA-registered, AABB-certified, and state-licensed. They work with local donors to contribute critical material to support medical breakthroughs. HemaCare Donor Centers process a variety of blood products including whole blood, bone marrow, white blood cells (apheresis) and mobilized white blood cells. These cells are collected and used worldwide in scientific research, drug development, and manufacturing for cell therapies. All donations are anonymous, and donors receive compensation for their time.

Combined with Charles River's integrated, early-stage portfolio of research models, discovery, safety assessment and CDMO cell and gene therapy manufacturing services, Charles River Cell Solutions provides cellular products and services, from research use to GMP-compliant products and consultative guidance, including cell processing and isolation services, creating clear pathways for client cell therapy or basic research objectives.

Approved Quotes

- "The CliniPrime Fresh Leukopak will help accelerate clients' work in the development of advanced therapeutics for clinical trials of potentially life-saving modalities of treatment." – Birgit Girshick, Executive Vice President and Chief Operating Officer, Charles River
- "In response to industry needs, the CliniPrime brand adds significant value to Charles River's portfolio of human derived cellular products. It provides clients rapid access to high-quality starting materials to support the development of cell, and gene-modified cell therapies." – Jeffrey Allen, Chief Vice President, Global Cell Therapy Solutions, 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 Contact:
Todd Spencer
Corporate Vice President,
Investor Relations
781.222.6455
todd.spencer@crl.com

Media Contact:
Amy Cianciaruso
Corporate Vice President,
Chief Communications Officer

781.222.6168
amy.cianciaruso@crl.com

Source: Charles River Laboratories International, Inc.