HemaCare Adds GMPrimeTM Cryopreserved Leukopak to its GMP Product Portfolio

June 2, 2020

Simplify complex study logistics with GMP-compliant cryopreserved leukopak for the development and commercialization of cell and gene therapies

LOS ANGELES--(BUSINESS WIRE)--Jun. 2, 2020-- HemaCare Corporation, a Charles River Laboratories International, Inc. (NYSE:CRL) company and global leader and trusted brand in the customization of human-derived biological products and services for biomedical research, drug discovery, and cellular therapy process development, today announced that it has expanded its portfolio of GMP-compliant cellular material with the launch of the GMPrime cryopreserved leukopak. The GMP-compliant cryopreserved leukopak includes a quality assurance (QA)-reviewed Certificate of Analysis, thus adding QA review to HemaCare's popular research use (HemaPrime ^{TM}) cryopreserved leukopak. HemaCare's GMPrime leukopaks are cryopreserved following a proprietary cryopreservation process and meet the requirements of the most rigorous quality standards required by regulatory agencies. GMPrime cryopreserved leukopaks extend shelf life and stability and provide researchers and cell therapy developers with the consistency needed in a cellular starting material used for the development and commercialization of next-generation cell and gene therapies.

Maintaining optimal function of key raw materials used to develop cell-based therapies is of prime importance. Factors such as site-to-site or international shipping of fresh leukopaks will impact cell viability and function. Cryopreserving a leukopak directly following collection significantly improves complex logistical hurdles by protecting product quality, mitigating risks during shipping, and allowing scheduling flexibility when planning and coordinating downstream processing activities, ultimately giving researchers and clinicians the freedom to plan, prepare, and perform studies on their timelines while preserving viability and functionality.

"Cryopreservation of leukopaks plays a critical role in the research and development continuum as this process simplifies complex logistics typically involved in working with raw human starting materials such as shipping, planning, and resource allocation while also providing the consistency, stability, and quality the industry desires," said Dominic Clarke, Ph.D., Global Head of Cell Therapy for HemaCare. *"The launch of HemaCare's GMPrime cryopreserved leukopak ensures the industry experiences a flexible and seamless transition as they move their therapy from research to commercialization."*

GMPrime cryopreserved leukopaks are collected within HemaCare's FDA-registered collection center from IRB-consented donors and immediately cryopreserved onsite within Class A and B (ISO 5 and 6) cleanroom environments. HemaCare's HemaPrime and GMPrime cryopreserved leukopaks adhere to the same stringent quality standards and are collected and processed following standardized protocols to ensure the highest achievable purity, viability, and quality thus ensuring researchers can seamlessly transition from development to clinical trials to commercialization with confidence.

Click here to learn more about GMPrime cryopreserved leukopak or contact our customer support team.

About HemaCare

HemaCare, a Charles River company, is a global leader in the supply and customization of human-derived biological products and services for biomedical research, drug discovery, and cellular therapy process development. Through our network of collection centers with access to an extensive recallable and reliable donor network, our dedicated employees provide clients with the cellular material they need for the development of the next generation of cell and gene therapies. Combined with Charles River's integrated, early-stage portfolio of discovery, safety assessment, and manufacturing support services, we provide customers comprehensive solutions from discovery through commercialization. To learn more about our portfolio and services, visit www.hemacare.com.

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, Public Relations
781-222-6168
amy.cianciaruso@crl.com

Business Development Contact:
Kimberly Negrin, Ph.D.

Associate Sales Director, Cell Therapy
617-817-6721
knegrin@hemacare.com

Source: HemaCare Corporation