Charles River and Vertex Pharmaceuticals Reach Important Milestone in Cell Therapy Manufacturing Collaboration

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Charles River's Memphis facility approved to manufacture Vertex's CASGEVY ™ therapy, the world's first gene-edited therapy targeting severe sickle cell disease

WILMINGTON, Mass. & MEMPHIS, Tenn.--(BUSINESS WIRE)--Dec. 18, 2023-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced an important milestone in their strategic collaboration to manufacture CASGEVY ™ (exagamglogene autotemcel [exa-cel]). CASGEVY is approved in some countries for certain eligible patients.

The news follows Charles River's Memphis center of excellence passing back-to-back audits from both the U.S. Food and Drug Administration (FDA) and the Health Products Regulatory Authority (HPRA), on behalf of the European Medicines Agency (EMA). The Memphis facility was the first North American contract development and manufacturing organization (CDMO) to be approved by the EMA to commercially manufacture an allogeneic cell therapy drug product.

"Our team in Memphis is proud to receive regulatory approval to manufacture CASGEVY," said James C. Foster, Chairman, President and Chief Executive Officer, Charles River. "We are pleased to reach this milestone working hand-in-hand with Vertex to manufacture the world's first gene-edited therapy. There is a tremendous patient need for this therapy and we look forward to working with Vertex to help bring this treatment to patients."

Leveraging CRISPR to Treat SCD
SCD is an inherited blood disease impacting millions of people worldwide. SCD affects hemoglobin, a part of the blood that carries oxygen around the body. People who suffer from this condition require lifelong treatment and significant use of health care resources, ultimately resulting in reduced life expectancy. Vertex collaborated with CRISPR Therapeutics to leverage the use of a gene-editing technology, known as CRISPR/Cas9, to discover and develop CASGEVY.

Cell Therapy Manufacturing Services
Charles River provides cell and gene-modified cell therapy developers with an efficient, robust, and scalable process to swiftly transition autologous and allogeneic programs to clinic and commercialization with one production partner.

In recent years, the Company has significantly broadened its cell and gene therapy portfolio with a substantial good manufacturing practice (GMP)-compliant commercial-ready capacity expansion and the integration of several strategic acquisitions to simplify complex supply chains and meet growing demand for plasmid DNA, viral vector, and cell therapy services. Combined with the Company's legacy testing capabilities, Charles River offers an industry-leading "concept-to-cure" advanced therapies solution.

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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