Charles River Laboratories is First CDMO in North America to Receive EMA Approval to Commercially Produce an Allogeneic Cell Therapy Drug Product

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Company awarded commercial GMP license following successful EMA inspection of Memphis CDMO facility

MEMPHIS, Tenn.--(BUSINESS WIRE)--Aug. 9, 2022-- Charles River Laboratories, International Inc. (NYSE: CRL) announced it has received regulatory approval, in the form of Good Manufacturing Practice (GMP) certification, to commercially produce allogeneic cell therapy drug products for distribution in Europe, from the European Medicines Agency (EMA).

The approval follows an inspection by the cell and gene therapy experts from the Italian inspectorate, Agenzia Italiana del Farmaco (AIFA), performed on the EMA's behalf. The GMP certification of Charles River's Memphis contract development and manufacturing (CDMO) facility complements an existing GMP license for Investigational Medicinal Product (IMP) production. The Memphis site can manufacture and ship drug products intended for European Union distribution. The approval recognizes Charles River's industry-leading expertise, multidisciplinary team, regulatory know-how, and quality standards.

Charles River's Memphis CGMP CDMO facility is suitable to manufacture clinical (early- and late-phase) as well as commercial cell and gene-modified cell therapies. With the 2021 acquisitions of Cognate BioServices, Cobra Biologics, and Vigene Biosciences, Charles River significantly expanded its cell and gene therapy portfolio to include end-to-end CDMO capabilities (plasmid DNA, viral vector, and cellular therapies). These capabilities have been integrated with Charles River's legacy services resulting in a "concept-to-cure" cell and gene therapy portfolio.

Approved Quotes

- "We are incredibly proud that our Memphis facility has received EMA approval to commercially manufacture an allogeneic cell therapy. We are looking forward to continuing close partnerships with our clients, and supporting future commercial projects, bringing these potentially curative therapies to patients, sooner." – Birgit Girshick, Corporate Executive Vice President & Chief Operating Officer, Charles River
- "Our team in Memphis has worked extremely hard to successfully complete the EMA inspection and authorization process. We are excited to be the first CDMO in North America to reach this milestone." –Will Isom, Site Director, Memphis, 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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