Charles River Collaborates with Patient Advocacy Group, FOXG1 Research Foundation to Advance Rare Disease Gene Therapy Development

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Clinical trials for AAV9 gene therapy bolstered with plasmid and viral vector CDMO expertise

WILMINGTON, Mass.--(BUSINESS WIRE)--Jul. 30, 2024-- Charles River Laboratories International, Inc. (NYSE: CRL) announced today a collaboration with the FOXG1 Research Foundation (FRF) highlighting the patient advocacy group's model to independently drive drug development through the clinical phase. The parent-led global organization driving the research to cure FOXG1 syndrome and related neurological disorders will collaborate with Charles River in a comprehensive gene therapy contract development and manufacturing organization (CDMO) agreement.

"Charles River is proud to work with the FOXG1 Research Foundation to advance its gene-therapy through clinical trials," said Kerstin Dolph, Corporate Senior Vice President, Global Manufacturing, Charles River. "The FOXG1 patient population has an incredible unmet need, and we are looking forward to lending our expertise to FRF as they continue to trailblaze a path toward providing rare disease treatments."

Through the collaboration, Charles River will provide FRF with access to extensive cell and gene therapy expertise and generate materials for FRF's Phase I-II adeno-associated viral (AAV) vector-based gene therapy clinical trials at its plasmid DNA and viral vector CDMO centers of excellence (CoE). The established CDMO will supply phase-appropriate High Quality (HQ) plasmid starting materials manufactured at its Alderley Park CoE in addition to good manufacturing practice (GMP) AAV9 viral vector manufactured at its Rockville CoE, leveraging an integrated manufacturing and biologics testing portfolio to streamline their path to the clinic.

"Given the limited investment for rare disease groups like ours, our foundation has created a model that allows us and other patient advocacy groups to operate like a virtual biotech company and independently and efficiently drive drug development," said Nasha Fitter, FOXG1 Parent, Co-founder and Chief Executive Officer, FOXG1 Research Foundation.

A New Approach to Drive Rare Disease Drug Development

Founded in 2017 and propelled by innovation and an urgency to accelerate the road to therapeutics for FOXG1 syndrome, FRF has created a replicable model for rare disease patient advocacy groups to take control and drive the development of treatments when no options exist. This includes pioneering novel AI platforms for patient data and streamlining preclinical work.

"The success of FRF's model is not only focused on operating as a highly efficient team, but also partnering with organizations that are equally passionate about bringing treatments to children with the highest unmet need and severe burden of disease. Selecting the right partner is critical and Charles River has demonstrated a deep understanding of our model and commitment to working on our therapies," continued Fitter.

FOXG1 syndrome is a severe rare neurological genetic disorder that greatly impacts early brain development and typically causes epilepsy and a host of medical complexities and disabilities. There are approximately 1,000 patients diagnosed with FOXG1 syndrome worldwide, with the diagnosis rate climbing steadily year-over-year and no approved treatments. Most children with FOXG1 syndrome cannot walk or talk or take care of their basic needs.

Cell and Gene Therapy CDMO Solutions

In recent years, Charles River has significantly broadened its cell and gene therapy portfolio with several acquisition integrations and expansions 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.

Presented live at the Charles River Cell and Gene Therapy Summit, March 19, 2024, in San Francisco, watch Nasha Fitter's FOXG1 Research Foundation Patient Story session on-demand, and explore the Summit resource hub: https://bit.ly/4bb2uDu

Also, listen to "A Mom's Mission", a Vital Science Podcast, broadcast July 16, 2024, where Nasha discusses the origins of FOXG1 Research Foundation, how daughter Amara's life has been shaped by her diagnosis, and how collaboration has helped advance their mission: https://bit.ly/3LuCpog

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.

About FOXG1 Research Foundation

The FOXG1 Research Foundation (FRF) is the global, parent-led rare disease patient organization dedicated to advancing treatments for FOXG1 syndrome and related disorders, while advocating for and supporting patients and families worldwide. FOXG1 syndrome is a rare neurological developmental disorder linked to Autism Spectrum Disorder, epilepsy, and developmental disabilities. Founded in 2017, FRF has rapidly emerged as a leader and innovator in the rare disease patient advocacy space, developing novel platforms and an efficient blueprint to accelerate drug development for rare diseases. As a Chan Zuckerberg Initiative partner and recognized through its CEO's presentation at the inaugural White House Rare Disease Forum, FRF is committed to radically improving the landscape for the 300 million patients affected by rare diseases worldwide.

www.foxg1research.org

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