

ViroCell and Great Ormond Street Hospital poised to unlock clinical trial ‘backlog’ following MHRA manufacturing approval

MHRA licence will enable global reach of ViroCell’s viral vectors for cell and gene therapy clinical trials

ViroCell’s manufacturing operations are housed within Great Ormond Street Hospital’s state-of-the-art GMP accredited unit for manufacturing cell and gene therapies, the Zayed Centre for Research

London, UK and New York, US, 1 November 2023 – ViroCell Biologics (“ViroCell” or the “Company”), a specialist contract development and manufacturing organisation (“CDMO”) for cell and gene therapy (CGT) clinical trials, announces that the Company is now able to manufacture and globally export viral vectors from Great Ormond Street Hospital’s (GOSH) state-of-the-art manufacturing facility, the Zayed Centre for Research, for use in clinical trials. This follows the grant of a Manufacturer’s Authorisation License (MIA) to GOSH to manufacture viral vectors by the UK’s Medicines and Healthcare products Regulatory Agency’s (MHRA).

Viral vectors are commonly used by CGT innovators to genetically modify human cells to create novel therapeutics. A lack of experienced capacity in viral vector supply, both in the UK and globally, has resulted in a shortage of lentivirus and gamma-retro viral vectors in the CGT market. This shortage in clinical trial vector supply is believed to be slowing the progress of bringing novel medicines to patients. With ViroCell now able to leverage GOSH’s state-of-the-art manufacturing facility, the Company is poised to relieve the strain on clinical research caused by the vector shortage and expand the supply of precisely engineered viral vectors for clinical trials.

ViroCell believes the significance of the current vector constraint on CGT clinical research in the UK is reflected by the MHRA’s issuance of the MIA to GOSH to manufacture viral vectors, as it continues to position the UK as a hub for life science innovation. The MHRA is widely considered a gold-standard regulatory authority, with its rigorous requirement for facility inspection and licencing for advanced therapy manufacturing for clinical trials. Therefore, in addition to accelerating CGT clinical trials in the UK, this approval could also help accelerate the start of new clinical trials worldwide, as ViroCell ramps up the manufacturing of vectors for global export.

The Zayed Centre for Research was established in 2019 and is a state-of-the-art GMP accredited unit for manufacturing CGTs, with seven specialist clean rooms. The facility houses the latest technologies to support ViroCell’s GMP manufacturing operations, creating a full-service model for the global supply of clinical grade viral vectors to researchers and industry alike.

John W. Hadden II, CEO at ViroCell, commented:

“Addressing the global viral vector supply/demand imbalance is a top priority for Team ViroCell as the scarcity of high-quality viral vectors has constrained the ability of innovators to manufacture their novel cell and gene therapies. This approval is an exciting milestone for ViroCell and GOSH, which should catalyse our next phase of growth as we unlock ViroCell’s full potential as the partner of choice for cell and gene therapy companies demanding precision engineered viral vectors produced to GMP standards. We highly value the MHRA’s collaboration and look forward to strengthening our partnership with GOSH as we work to help accelerate clinical trials for advanced therapy patient candidates around the world.”

Professor Claire Booth, Mahboubian Professor in gene therapy and paediatric immunology at GOSH and UCL GOS ICH, and Clinical Academic Lead for the Cell & Gene Therapy Service at GOSH, added:

“We are delighted that GOSH has been granted MHRA licensing for the manufacture of viral vectors. With our state-of-the-art facility and ViroCell’s international network of collaborators, vectors for both UK and global projects can be manufactured at the Zayed Centre for Research, unclogging the industry-wide bottleneck, accelerating cell and gene therapy clinical trials and expanding the novel treatments that we can offer to our patients.”

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Notes to editor:

ViroCell

www.virocell.com

ViroCell Biologics is an innovation-driven Contract Development and Manufacturing Organisation (“CDMO”) focused exclusively on the design and GMP manufacture of viral vectors for clinical trials. Built around one of the most prolific academic viral vector manufacturing teams, ViroCell was created to address the global demand for precisely engineered viral vectors and aims to become the partner of choice for companies developing cell and gene therapies. The team leverages its deep track record to help clients to de-risk and accelerate novel cell and gene therapies into and through clinical development, with a mission of being the partner of choice for corporate and academic innovators in this field. Focused initially on manufacturing lentivirus, gamma-retrovirus, and AAV vectors, ViroCell enables clients to start clinical trials on a scalable platform, delivering value by reducing costs, time and regulatory risk.

Great Ormond Street Hospital for Children NHS Foundation Trust

Founded in 1852, Great Ormond Street Hospital is one of the world’s leading children’s hospitals with the broadest range of dedicated, children’s healthcare specialists under one roof in the UK. With more than 252,000 outpatient and 43,000 inpatient visits every year, the hospital’s pioneering research and treatment gives hope to children from across the UK with the rarest, most complex and often life-threatening conditions. As an international centre of excellence in child healthcare, our patients and families are central to everything we do – from the moment they come through the door and for as long as they need us.

For more information, please visit www.gosh.nhs.uk

Zayed Centre for Research (ZCR) into Rare Disease in Children

The Zayed Centre for Research (ZCR) into Rare Disease in Children opened to patients in October 2019 thanks to a transformational £60m gift from Her Highness Sheikha Fatima bint Mubarak, wife of the late Sheikh Zayed bin Sultan Al Nahyan, Founder of the United Arab Emirates. It is the only Centre of its kind in the world and brings together pioneering research and clinical care under one roof to help drive forward new treatments and cures for children with rare diseases.

www.gosh.org/what-we-do/research/zayed-centre-research-rare-disease-children/

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