



MeiraGTx Announces MHRA Grants MIA (IMP) License for cGMP Manufacturing Facility in London, UK

June 21, 2018

LONDON and NEW YORK, June 21, 2018 (GLOBE NEWSWIRE) -- MeiraGTx Holdings Plc (NASDAQ:MGTX), a vertically integrated, clinical stage gene therapy company, today announced it has been granted a Manufacturer's Authorization for Investigational Medicinal Products from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). The license allows MeiraGTx to manufacture gene therapy product candidates in their current Good Manufacturing Practices (cGMP) compliant manufacturing facility.

Completed in early 2018, MeiraGTx's 29,000 square-foot facility located in central London was designed to operate as a flexible and scalable manufacturing hub, housing two cell production suites and three separate viral vector production suites, offering production of multiple product candidates in parallel, as well as sequentially at different scales.

"Manufacturing remains a significant bottleneck in the development and delivery of gene-based medicines to the market," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "We have strategically crafted in-house capabilities, encompassing both the manufacturing facility and hiring of an extremely talented team. We believe this will allow us to become a bedrock of production and collaboration for those working in gene therapy and bioprocessing. We are extremely grateful to have some of the industry's best manufacturing experts leading our operations."

The facility also incorporates an integrated analytical department, an in-house analytical tool kit, and a dedicated product fill-and-finish suite. MeiraGTx's facility has been designed to meet MHRA, European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) regulatory standards.

"At MeiraGTx, we understand how critically important and in-demand manufacturing is for the global cell and gene therapy industry," said James Christie, BSc, MBA, SVP manufacturing and supply chain of MeiraGTx. "With our capabilities to produce, scale and analyze product candidates, MeiraGTx is well positioned to expedite the delivery of potential therapies to researchers, physicians and ultimately patients. We are excited about the advantage this facility creates in helping us optimize the best potential therapies for patients."

About MeiraGTx

MeiraGTx (NASDAQ:MGTX) is a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs and a broad pipeline of preclinical and research programs. MeiraGTx has core capabilities in viral vector design and optimization and gene therapy manufacturing, as well as a potentially transformative gene regulation technology. Led by an experienced management team, MeiraGTx has taken a portfolio approach by licensing, acquiring and developing technologies that give depth across both product candidates and indications. MeiraGTx's initial focus is on three distinct areas of unmet medical need: inherited retinal diseases, severe forms of xerostomia and neurodegenerative diseases. Though initially focusing on the eye, salivary gland and central nervous system, MeiraGTx intends to expand its focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

For more information, please visit www.meiragtx.com

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. The information contained in this press release is believed to be current as of the date of original issue. MeiraGTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Contacts

Investors:
MeiraGTx
investors@meiragtx.com

or

Media:
W2O pure
Kelly Boothe, (415) 946-1076
kboothe@w2ogroup.com

 Primary Logo

Source: MeiraGTx