MeiraGTx Announces its Wholly-Owned Gene Therapy Manufacturing Facility in Shannon, Ireland has Received Commercial MIA Authorization for QC Testing

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LONDON and NEW YORK, July 19, 2023 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced that after a successful inspection by the Irish Health Products Regulatory Authority (HPRA), it has received a Commercial Manufacturer's/Importer's Authorization (MIA) for its Quality Control (QC) testing facility at its GMP manufacturing site in Shannon, Ireland.

"Receiving our first commercial license for our state-of-the-art manufacturing facility in Shannon so rapidly is another testament to the quality of the MeiraGTx team and our industry leading end-to-end capabilities," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "This certification not only enables us to accelerate the development and delivery of our own pipeline of gene therapies for a range of serious conditions, but it also provides potential for MeiraGTx to generate additional revenue as the industry faces increasing delays and shortages of licensed, reliable QC testing for advanced therapies globally."

Unique in its scale and integrated capabilities and stretching over 150,000 square feet, the GMP Shannon facility is Ireland's first commercial-scale gene therapy manufacturing site and contains three facilities. The first facility was built to be a flexible and scalable center for viral vector production for clinical and commercial supply. The second facility was built to manufacture plasmid DNA – the critical starting material for producing gene therapy products. The third facility serves as a QC hub performing advanced biochemical quality control testing for release and stability testing for MeiraGTx and its partners' clinical and commercial programs.

About MeiraGTx
MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage gene therapy company with six programs in clinical development and a broad pipeline of preclinical and research programs. MeiraGTx has core capabilities in viral vector design and optimization and in-house gene therapy GMP manufacturing facilities in London, United Kingdom and Shannon, Ireland, and a transformative gene regulation platform technology that allows precise, dose responsive control of gene expression by oral small molecules with dynamic range that can exceed 5000-fold. 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: ocular diseases, including both inherited retinal diseases as well as large degenerative ocular diseases, neurodegenerative diseases and severe forms of xerostomia. Though initially focusing on the eye, central nervous system and salivary gland, MeiraGTx plans to expand its focus to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

Forward Looking Statement
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our product candidate development and anticipated milestones regarding our pre-clinical and clinical data, reporting of such data and the timing of results of data and regulatory matters, as well as statements that include the words "expect," "will," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "could," "should," "would," "continue," "anticipate" and similar statements of a future or forward-looking nature. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, our incurrence of significant losses; any inability to achieve or maintain profitability, raise additional capital, repay our debt obligations, identify additional and develop existing product candidates, successfully execute strategic priorities, bring product candidates to market, expansion of our manufacturing facilities and processes, successfully enroll patients in and complete clinical trials, accurately predict growth assumptions, recognize benefits of any orphan drug designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of the COVID-19 pandemic on the status, enrollment, timing and results of our clinical trials and on our business, results of operations and financial condition; failure of early data to predict eventual outcomes; failure to obtain FDA or other regulatory approval for product candidates within expected time frames or at all; the novel nature and impact of negative public opinion of gene therapy; failure to comply with ongoing regulatory obligations; contamination or shortage of raw materials or other manufacturing issues; changes in healthcare laws; risks associated with our international operations; significant competition in the pharmaceutical and biotechnology industries; dependence on third parties; risks related to intellectual property; changes in tax policy or treatment; our ability to utilize our loss and tax credit carryforwards; litigation risks; and the other important factors discussed under the caption "Risk Factors" in our most recent quarterly report on Form 10-Q or annual report on Form 10-K or subsequent 8-K reports, as filed with the Securities and Exchange Commission. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, unless required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Contacts

Investors:
MeiraGTx
Investors@meiragtx.com

or

Media:
Jason Braco, Ph.D.
LifeSci Communications
jbraco@lifescicomms.com