MeiraGTx's Industry-Leading Gene Therapy Manufacturing Facility in Shannon, Ireland Formally Introduced by Head of Irish Government

September 16, 2022

-- Manufacturing facilities built to accelerate development and delivery of advanced medicines to patients using state-of-the-art technology at scale, with quality appropriate for commercialization

-- Site reflects MeiraGTx's unique, end-to-end approach to gene therapy manufacturing to expedite clinical development

LONDON and NEW YORK, Sept. 16, 2022 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (NASDAQ: MGTX), a vertically integrated, clinical stage gene therapy company, will today formally unveil its GMP manufacturing facility in Shannon, Ireland, with the Head of Irish Government, Micheál Martin, in attendance.

The facility, online since earlier this year and stretching over 150,000 square feet, is the first commercial-scale gene therapy manufacturing site in Ireland. The facility is unique in its scale and integrated capabilities. The site contains three facilities, one built to be flexible and scalable for viral vector production for clinical and commercial supply, in addition, a facility to manufacture plasmid DNA – the critical starting material for producing gene therapy products – and thirdly, a Quality Control (QC) hub performing advanced biochemical quality control testing for MeiraGTx clinical and commercial programs.

The formal unveiling marks a critical step in MeiraGTx's mission to develop and deliver potentially curative treatments for patients living with serious diseases. The Shannon site allows MeiraGTx to accelerate the development and delivery of gene therapy treatments to patients facing a wide range of both genetic and non-hereditary disorders – ranging from inherited vision loss, salivary-gland conditions, and neurological diseases such as Parkinson's, to potentially diabetes, obesity, and some cancers.

By building end-to-end gene therapy development, testing and manufacturing capabilities in-house, MeiraGTx has put in place the infrastructure and technology required to avoid bottlenecks in clinical development, reduce regulatory risk, and ensure the highest quality products for patients – all while lowering costs. The facility will also allow MeiraGTx the ability to provide manufacturing services to potential collaborators, helping to lessen the impact of industry-wide shortages of vital elements such as plasmid DNA and quality control services.

The facility, which is set to employ 100 people in its current phase, with the potential for that to increase to over 300, has been sited in Shannon due to its proximity to a number of world-class bioscience institutions, as well as partner companies in the healthcare sector. MeiraGTx is proud to have collaborated with The University of Limerick and the National Institute for Bioprocessing Research and Training (NIBRT) on skills and capability development and looks forward to building ever-closer relationships with other leading institutions across Ireland.

During the unveiling today, the Head of the Irish Government will meet senior leaders from MeiraGTx, undertake a walking tour of the facility and make a short address to invited guests.

Head of Irish Government, Micheál Martin, said:

"Today is an important day for MeiraGTx in Ireland, as we mark the formal unveiling of their state-of-the-art manufacturing facility. Great strides are being made in the area of gene therapy and I've no doubt that these new facilities will allow MeiraGTx to remain at the forefront of that development. Today's unveiling is testament to the company's continued commitment to Shannon and the Mid-West and speaks to the considerable skills and ability of the Irish workforce."

Alexandria Forbes, Ph.D., President, and Chief Executive Officer of MeiraGTx, said:

"MeiraGTx's Shannon facility is unique, not only in Ireland but globally, as it streamlines gene therapy development, testing and manufacturing capabilities together in-house. This significantly reduces the time to patients for advanced therapeutic products, with months or potentially years saved. Along with our other facilities in New York, London and Amsterdam, the Shannon site will scale up and manufacture a broad range of gene therapies for people living with a variety of serious conditions."

Alastair Leighton, Ph.D., Senior Vice President of Manufacturing and Supply Chain at MeiraGTx, said:

"The COVID-19 pandemic has placed a strain on the global gene therapy industry to manufacture critical components, as well as exposed the shortcomings in the supply chain. While vaccines are not gene therapies, they share many of the same manufacturing processes and resources. The Shannon facility has been designed to address these challenges in order to provide access to transformative potential medicines to patients as well as be ready for significant future expansion."

CEO of IDA Ireland Martin Shanahan said:

"In 2020, MeiraGTx announced its intention to locate this globally unique GMP manufacturing facility in Shannon. So, it's terrific that two years later we can celebrate this official unveiling. IDA Ireland remains committed to winning jobs and investments across the country and MeiraGTx's decision to locate in the Mid-West demonstrates the region's reputation as a key location for the next generation of biopharmaceutical manufacturers."

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 gene therapy manufacturing, and a transformative gene regulation platform technology which 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.

For more information, please visit www.meiragtx.com

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 the use of our manufacturing facilities in Shannon, Ireland, including in light of the COVID-19 pandemic, 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

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