



MeiraGTx to Present Clinical Data from Phase 1 Trial of AAV-hAQP1 for Radiation-Induced Xerostomia on Tuesday, December 13, 2022

December 08, 2022

LONDON and NEW YORK, Dec. 08, 2022 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (NASDAQ: MGTX), a vertically integrated, clinical stage gene therapy company, today announced it will host a conference call and webcast to present clinical data from the Company's AAV-hAQP1 Phase 1 AQUAx clinical trial for the treatment of radiation-induced xerostomia (RIX) on Tuesday, December 13, 2022, at 8:00 a.m. ET.

The Phase 1 AQUAx conference call will also include a clinical program update for product candidate AAV-hAQP1, a potential treatment for RIX, from MeiraGTx's senior management and lead investigator Michael Brennan, DDS, Chairman of the Department of Oral Medicine and Director of the Sjögren's Syndrome and Salivary Disorders Center at Atrium Health Carolinas Medical Center.

A question-and-answer session will follow the formal presentation.

The presentation will include a summary of the following information for the 24 patients treated with AAV-hAQP1 in both Unilateral and Bilateral treated cohorts in the Phase 1 AQUAx clinical study:

- Safety and tolerability data
- PRO assessments of xerostomia symptoms
- Objective measure of changes in saliva flow
- Full 12-month data for Unilateral cohorts (n=12)
- Full 6-month data for Bilateral cohorts (n=12)
- Long-term data to 2 or 3 years for the small number of subjects who have reached those timepoints

To register and attend the event, please click [here](#).

A live webcast of the call, as well as a replay, will be available on the Investors page of the Company's website at www.investors.meiragtx.com/.

About the Phase 1 AQUAx Clinical Trial

The Phase 1 AQUAx clinical trial is an open-label, non-randomized, dose escalation trial designed to evaluate the safety of MeiraGTx's investigational gene therapy AAV-hAQP1 when administered via Stensen's duct to one or both parotid glands in patients who have been diagnosed with grade 2 or 3 radiation-induced xerostomia and who have remained cancer free for at least five years (or at least two years if HPV+) after receiving radiation treatment for head and neck cancer. Primary endpoint of the trial is safety, with efficacy endpoints including the evaluation of the change in parotid gland salivary output after treatment with AAV-hAQP1 and patient reported measures of xerostomia symptoms.

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 tight, 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, including inherited retinal diseases and 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 the development of AAV-hAQP1 and our clinical data and reporting of such data and the timing of results of data, 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. Unless otherwise stated or the context otherwise requires, the information herein is as of December 8, 2022.

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