MeiraGTx Enters into a Strategic Collaboration with Hologen AI to Expedite Phase 3 Development of AAV-GAD for Parkinson's Disease and Industrialize MeiraGTx's Proprietary Manufacturing Process

March 13, 2025

- MeiraGTx to receive $200 million in upfront cash consideration

- MeiraGTx and Hologen will form a joint venture, Hologen Neuro AI Ltd, with an additional $230 million committed capital from Hologen to fund 100% of the development of AAV-GAD for Parkinson's disease through to commercialization, as well as other potential pipeline products

- MeiraGTx will enter into clinical and commercial supply agreements with Hologen Neuro AI Ltd to manufacture AAV-GAD and other locally delivered CNS genetic medicines

- Hologen will also fund a portion of MeiraGTx's manufacturing operations and will own a minority stake in MeiraGTx's manufacturing subsidiary

LONDON and NEW YORK, March 13, 2025 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage genetic medicines company, today announced a broad strategic collaboration with Hologen Limited, a world-leading developer of multi-modal generative AI foundation models of real-world clinical data for clinical medicine and pharmaceutical drug development.

MeiraGTx will receive $200 million in upfront cash at closing and MeiraGTx and Hologen are forming a joint venture, called Hologen Neuro AI Ltd. In addition to the $200 million upfront payment to MeiraGTx, the joint venture, Hologen Neuro AI Ltd, will be funded with committed capital of up to $230 million from Hologen to fully finance the development of AAV-GAD for the treatment of Parkinson's disease through to commercialization, as well as funding earlier stage clinical programs in the CNS, including AAV-BDNF for genetic obesity. Hologen will contribute its proprietary multi-modal generative foundation models (LMMs) to the joint venture. In forming this joint venture, MeiraGTx and Hologen have created the first neuro-AI clinical drug development company in which pioneering technologies from both companies will be deployed to transform the discovery and development of therapies targeting CNS circuitry in neurodegenerative and neuropsychiatric disorders.

MeiraGTx will retain 30% ownership in the Hologen Neuro AI Ltd joint venture and will lead all clinical development and manufacturing. MeiraGTx will also enter into exclusive clinical and commercial manufacturing supply agreements with the joint venture. In addition, Hologen will own a minority stake in MeiraGTx's manufacturing subsidiary and will contribute to the annual funding of the manufacturing subsidiary. Hologen is deploying its generative AI capabilities to further optimize MeiraGTx's proprietary manufacturing capabilities by utilizing MeiraGTx's unique data lakes built over 9 years of development of MeiraGTx's manufacturing platform process.

MeiraGTx's AAV-GAD program for Parkinson's disease is Phase 3 ready with commercial manufacturing ongoing in-house at MeiraGTx. The Company reported positive data from its randomized, sham-controlled clinical bridging study of AAV-GAD in October 2024, showing significant improvement of 18 points in Unified Parkinson's Disease Rating Scale (UPDRS) Part 3 in the high dose group at 26 weeks, as well as significant improvement in the Parkinson's Disease Questionnaire (PDQ-39) score, a key quality of life measure, for both the high and low dose groups at 26 weeks. This is the second double blind sham-controlled study of AAV-GAD in Parkinson's disease to show a statistically significant benefit on UPDRS Part 3, as well as other validated clinically meaningful endpoints.

Alexandria Forbes, Ph.D., co-founder, president and CEO of MeiraGTx stated, "We are delighted to be entering into this transformative collaboration with Hologen. Our initial focus is to increase the robustness, efficiency and probability of success of the AAV-GAD Phase 3 clinical study. The use of Hologen's AI to elucidate brain circuitry in this complex heterogeneous disease has already significantly de-risked the AAV-GAD Phase 3 program when applied to MeiraGTx's Phase 2 clinical data sets and has identified disease modifying changes in the physiology of the brain in response to AAV-GAD treatment."

Dr. Forbes continued, "Our collaboration with Hologen has broad significance for MeiraGTx and for drug development for neurological disorders in general. Deploying Hologen's LMMs on MeiraGTx's clinical data allows the characterization of disease modification in the CNS with unprecedented fidelity. This collaboration joins two incredibly innovative technologies to advance the potential for the development of drugs that have meaningful impact on neurodegenerative and neuropsychiatric diseases which have been largely intractable to effective treatment to date."

Dr. Forbes added, "From a financial perspective, this is a transformative transaction for MeiraGTx, providing $200 million in cash to MeiraGTx and at the same time funding a proportion of our internal manufacturing capabilities, as well as providing the additional capital into the newly established joint venture to fully finance the AAV-GAD program, while MeiraGTx retains significant equity value in the fully funded late-stage Neuro-AI company. The upfront capital will meaningfully extend MeiraGTx's cash runway while allowing us to further expedite our pivotal AAV-hAQP1 Xerostomia program for which we received an RMAT designation in December 2024. We also expect this funding to help us accelerate the development of our Riboswitch technology supported by our compelling data in metabolic disease, cell therapy, neuropathic pain and heart disease - all very large areas of medical need amenable to phasic *in vivo* delivery of native biologic therapeutics."

Collaboration Details and Financial Terms:

- MeiraGTx will receive $200 million in upfront cash consideration at closing.
- MeiraGTx and Hologen will form a joint venture, Hologen Neuro AI Ltd, with additional committed funding into the joint venture of up to $230 million from Hologen to finance the development of the AAV-GAD program in Parkinson's disease through to commercialization, as well as other locally-delivered therapies to the CNS.

- The joint venture, Hologen Neuro AI Ltd, will use Hologen's proprietary multi-modal generative foundation models (LMMs).
- MeiraGTx will hold a 30% ownership in the joint venture and will lead all clinical development and manufacturing.
- Hologen Neuro AI Ltd will enter into both clinical and commercial manufacturing supply agreements with MeiraGTx for exclusive manufacturing of AAV-GAD and other locally-delivered genetic medicines targeting the CNS.
- Hologen will own a minority stake in MeiraGTx's manufacturing subsidiary and will contribute a portion of the annual funding and deploy Hologen's world leading generative AI capabilities to further accelerate the optimization of MeiraGTx's proprietary manufacturing capabilities.
- The transactions described above are subject to customary closing and funding conditions, including the receipt of the clearances and approvals applicable to the proposed transactions under the foreign direct investment laws of the United Kingdom and the satisfaction or waiver of certain other closing conditions, and is expected to close in the second calendar quarter of 2025.

About MeiraGTx
MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage genetic medicines company with a broad pipeline with four late-stage clinical programs. Each of these programs use local delivery of small doses resulting in disease modifying effects in both inherited and more common diseases, in the eye, Parkinson's disease and radiation-induced xerostomia. MeiraGTx uses its innovative technology in optimization of capsids, promoters and novel translational control elements to develop best in class, potent, safe viral vectors. MeiraGTx's broad pipeline is supported by end-to-end in-house manufacturing. MeiraGTx has built the most comprehensive manufacturing capabilities in the industry, with 5 facilities globally, including two that are licensed for GMP viral vector production and a GMP QC facility with clinical and commercial licensure. In addition, MeiraGTx has developed a proprietary manufacturing platform process over 9 years based on more than 20 different viral vectors with leading yield and quality aspects and commercial readiness. Uniquely, MeiraGTx has developed a novel technology for *in vivo* delivery of any biologic therapeutic using oral small molecules. This transformative riboswitch gene regulation technology allows precise, dose-responsive control of gene expression by oral small molecules. MeiraGTx is focusing the riboswitch platform on the regulated *in vivo* delivery of metabolic peptides, including GLP-1, GIP, Glucagon, Amylin, PYY and Leptin, as well as cell therapy, CAR-T for liquid and solid tumors and autoimmune diseases, and additionally PNS targets addressing long term intractable pain. MeiraGTx has developed the technology to apply genetic medicine to common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains high.

For more information, please visit www.meiragtx.com

About Hologen
Hologen Limited is a world-leading developer of generative AI capabilities for clinical medicine and pharmaceutical drug development. Hologen builds the largest, most expressive, accurate, and equitable generative AI models in healthcare, using large real-world clinical and research data sets from multiple modalities. Hologen's Large Medical Models learn the rich biological diversity of healthy and pathological variation in unprecedented breadth and detail. By capturing complex biological heterogeneity with high fidelity, as revealed by clinical data, Hologen's technology overcomes the insensitivity of interventional trials, enabling accurate quantification of therapeutic effects, and illuminates disease mechanisms opaque to conventional models, revealing new therapeutic and commercial opportunities. In Phase 2 and Phase 3 trials, the technology is used to increase trial success probabilities substantially and to gain much greater control over trial design and approvability. The company emerged as a spin-out from University College London and Kings College London. It is privately held.

For more information, please visit www.hologen.ai

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 collaboration, including the anticipated timing for its closing and funding thereunder, the success of the activities to be performed under the collaboration, the efficacy of Hologen's AI technology, the development of our AAV-GAD, AAV-BDNF and other CNS product candidates and the development of our manufacturing technology, 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 transactions or 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 or rare pediatric disease designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of pandemics, epidemics or outbreaks of infectious diseases 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 Annual Report on Form 10-K for the year ended December 31, 2024, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. 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.

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