Complement Therapeutics Announces Completion of Cohort 1 Dosing and Favourable Independent Data Monitoring Committee Recommendation in the Phase I/II Opti-GAIN Study for Geographic Atrophy Secondary to AMD

- Cohort 1 enrolment completed in the Company's first-in-human Opti-GAIN clinical trial of CTx001 in Geographic Atrophy (GA) secondary to AMD
- The Independent Data Monitoring Committee (IDMC) has recommended proceeding with dose escalation after planned safety assessment of first dose cohort
- CTx001 is an investigational AAV gene therapy that potently downregulates multiple complement pathways and has the potential to be a highly differentiated approach to the treatment of GA secondary to AMD.
- Opti-GAIN is among the first GA studies to prospectively evaluate ellipsoid zone (EZ) integrity as well as the focal microperimetry as primary structural and functional endpoints

Munich, Germany - 27 May 2026 - Complement Therapeutics GmbH (CTx), a clinical-stage biotechnology company developing next-generation therapeutics for complement-mediated diseases, today announced the completion of dosing for Cohort 1 in the Opti-GAIN clinical trial of CTx001 in patients with Geographic Atrophy (GA) secondary to Age-related Macular Degeneration (AMD).

The Company also announced that the IDMC has completed its review of safety data from Cohort 1, identified no significant safety concerns, and recommended that enrolment in Cohort 2 proceed.

"Completing enrolment in Cohort 1 and receiving a favourable IDMC recommendation are together an important step forward for Opti-GAIN and for CTx001," said Dr Rafiq Hasan, Chief Executive Officer of Complement Therapeutics. "The IDMC's review provides the first external validation of CTx001's safety profile in human subjects, and we are very pleased to have received a recommendation to proceed. With Cohort 2 now open, we continue to advance the dose-escalation phase whilst looking forward to reporting important updates in the second half of 2026. Importantly, the novel endpoints we are deploying, particularly EZ integrity and focal microperimetry assessed against each patient's own pre-treatment baseline, are designed to give us the most sensitive possible read on whether CTx001 can demonstrate potential efficacy."

Opti-GAIN employs a differentiated endpoint strategy designed to sensitively evaluate structural and functional changes following subretinal gene therapy at the level of the individual patient. The study is among the first in Geographic Atrophy to prospectively evaluate two novel endpoints:

- Ellipsoid Zone (EZ) Integrity: A structural assessment reflecting the health of photoreceptors with the potential to provide an early and sensitive measure of structural disease progression and potential treatment effects of CTx001.

- Focal Optical Coherence Tomography (OCT) - based Microperimetry: A functional assessment that precisely maps retinal sensitivity in areas of geographic atrophy, providing a more sensitive and clinically meaningful assessment of functional change before and after administration of CTx001 within the treated eye.

"The novel design characteristics of the Opti-GAIN study have the ability to provide an early indication of the safety, tolerability and potential efficacy of CTx001 in GA secondary to AMD. This process is now well underway with encouraging early data from the first cohort and patients already in the run-in for upcoming dosing." said M. Ali Memon, Chief Medical Officer of Complement Therapeutics.

The Opti-GAIN and Pre-GAIN studies are being conducted by the company's UK subsidiary. More information is available at ClinicalTrials.gov, including Opti-GAIN (NCT07392255) and Pre-GAIN (NCT07144137).

About the CTx001 program

CTx001 is an investigational AAV2-based gene therapy in development for Geographic Atrophy secondary to Age-related Macular Degeneration. The therapy is designed to deliver mini-CR1, a truncated and secreted form of Complement Receptor 1, to enable sustained local modulation of multiple complement pathways following a single subretinal injection.

About the Opti-GAIN Trial

Opti-GAIN is a Phase I/II multi-centre clinical study evaluating the safety, tolerability and efficacy of CTx001 administered via a single subretinal injection in 75 participants with Geographic Atrophy secondary to Age-related Macular Degeneration. Safety and efficacy will be assessed regularly over 2 years, followed by annual long-term safety follow-up for up to 5 years.

About the Pre-GAIN Trial

Pre-GAIN is a multi-centre, non-interventional, natural history study designed to provide insights into the short-term progression of Geographic Atrophy secondary to Age-related Macular Degeneration. The study is intended to characterise structural and functional measures of GA progression and may help identify participants for Opti-GAIN.

About Geographic Atrophy

Geographic Atrophy (GA) is a leading cause of blindness in the elderly and represents the advanced stage of dry age-related macular degeneration. It is characterised by the progressive degeneration of photoreceptors, retinal pigment epithelium, and choriocapillaris, resulting in irreversible vision loss. GA affects over 5 million people globally and remains a significant unmet clinical need.

About Complement Therapeutics GmbH:

Complement Therapeutics GmbH (CTx) is a German-headquartered clinical-stage biotechnology company focused on the research and development of novel therapeutics for complement-

mediated diseases. The Company is a spinout from the University of Manchester and is based on the pioneering research of its founders into novel targets within the complement cascade.

Our lead investigational product (CTx001) is being evaluated as a potential gene therapy for GA, a leading cause of blindness. Additional programs will evaluate potential therapeutic opportunities in other complement-mediated conditions.

The Company has subsidiaries in the UK (Complement Therapeutics Ltd) and in the USA (Complement Therapeutics Inc) as well as research laboratories in Stevenage, UK.

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For more information please visit: https://complementtx.com/

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