Complement Therapeutics Announces Completion of Cohort 2 Dosing and Favourable IDMC Recommendation to Proceed to High Dose and Expansion Cohorts in the Phase I/II Opti-GAIN Study

- CTx001 is an investigational AAV gene therapy being developed for Geographic Atrophy (GA) secondary to Age-related Macular Degeneration (AMD)
- The Independent Data Monitoring Committee (IDMC) identified no significant safety concerns and recommended proceeding simultaneously with escalation to the high dose cohort; and with the dose expansion phase of the Opti-GAIN study
- CTx001 continues to be well tolerated across both dose cohorts evaluated to date

Munich, Germany - 1 Sep 2026 - Complement Therapeutics GmbH (CTx), a clinical-stage biotechnology company developing next-generation therapeutics for complement-mediated diseases, today announced that dosing is complete in Cohort 2 of the Opti-GAIN Phase I/II clinical trial of CTx001 in patients with GA secondary to AMD. The IDMC has completed its review of Cohorts 1 and 2 safety data, identified no significant safety concerns, and recommended that the study proceed in tandem to Cohort 3, the highest planned dose level in the dose-escalation phase; as well as the first dose expansion (Cohort 4). Six patients have been dosed with CTx001 in Opti-GAIN to date across 2 dose cohorts (low and medium dose). An additional three patients will be dosed at the high dose in Cohort 3, completing the dose-escalation phase of the study.

"Reaching the highest planned dose and receiving a recommendation to open our first expansion cohort is a defining moment for the Opti-GAIN programme and for the millions of people living with GA, a condition where the need for treatments that meaningfully preserve vision remains substantial. Advancing through two dose levels without a safety signal is a credit to our clinical team and our investigators. We now look forward to completing dose escalation and initiating the dose expansion phase of the study," said Dr Rafiq Hasan, Chief Executive Officer of Complement Therapeutics.

Opti-GAIN employs a differentiated endpoint strategy designed to detect structural and functional change at the level of the individual patient. Alongside safety data, the study prospectively evaluates ellipsoid zone (EZ) integrity and focal OCT-based microperimetry, each assessed against the patient's own pre-treatment baseline, enabling earlier detection of potential treatment effects than conventional measures such as lesion growth.

"We have seen no drug-related clinically significant safety findings across either dose cohort, and the IDMC's recommendation to escalate to the highest planned dose reflects that. Just as importantly, our EZ-based microperimetry assessments are generating the granular, patient-

level data we designed the study to capture. We look forward to sharing preliminary findings from the initial cohorts in the coming months," said Dr 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).

– Ends –

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.

Opti-GAIN is among the first GA studies to prospectively evaluate two novel endpoints: Ellipsoid Zone (EZ) Integrity, a structural assessment reflecting photoreceptor health with the potential to provide an early and sensitive measure of disease progression and treatment effect; and Focal OCT-based Microperimetry, a functional assessment that precisely maps retinal sensitivity in areas of geographic atrophy. Both are assessed against each patient's own pre-treatment baseline data.

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 programmes 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.

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

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