OPT-302-1002 Clinical Trial Summary – Phase 2B Wet AMD

Protocol Number	OPT-302-1002
Title	A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with neovascular age-related macular degeneration (wet AMD)
Sponsor	Opthea Limited
Indication	Neovascular (wet) age-related macular degeneration (AMD)
Study Phase	2b
Primary Objective	To determine the efficacy of two different doses of intravitreal OPT-302 when administered in combination with ranibizumab in participants with wet AMD
Primary Endpoint	Mean change from Baseline in Early Treatment Diabetic Retinopathy Study (ETDRS) best corrected visual acuity (BCVA) to Week 24
Secondary Endpoints	• The proportion of participants gaining 15 or more ETDRS BCVA letters from Baseline to the Week 24 Visit • Area under the ETDRS BCVA-over-time curve • Change in CST on SD-OCT from Baseline to Week 24 • Change in sub-retinal fluid on SD-OCT from Baseline to Week 24 • Presence or absence of intra-retinal fluid determined by the presence or absence of intra-retinal cysts on SD-OCT from Baseline to Week 24 • Proportion of participants losing 15 or more letters (on ETDRS BCVA chart) from Baseline to the Week 24 Visit • Incidence of ocular and non-ocular adverse events (AEs) • OPT-302 pharmacokinetic parameters • Participant incidence of ADA formation
Study Design	Multicentre, randomised, parallel-group, sham-controlled, double-masked, dose-ranging study
Investigational Product	OPT-302
Comparator	Ranibizumab (Lucentis®)
Control	Sham control
Study Arms	Three study arms, randomised in a 1:1:1 ratio (every 4 weeks for 6 treatment cycles via sequential intravitreal injection): • OPT-302 2 mg, with ranibizumab 0.5 mg, • OPT-302 0.5 mg, with ranibizumab 0.5mg, • Sham intravitreal injection, with ranibizumab 0.5 mg
Clinical Trial Sites	Approximately 113 sites in USA, Europe and Israel
Key Eligibility Criteria	• Participants ≥ 50 years of either gender, with active CNV secondary to AMD confirmed by fluorescein angiography (FA), who are treatment naïve. • An ETDRS BCVA score between 60 and 25 (inclusive) letters