Table C-30. Ongoing clinical trial of implantable miniature telescope

Clinicaltrials.gov Title Clinicaltrials.gov Identifier Sponsor	Study Design	Purpose	Start Date Expected Completion Date Estimated Enrollment	Primary Outcomes	Secondary Outcomes	Eye-specific Inclusion Criteria	Eye-specific Exclusion Criteria
Post-approval Study of VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment Assoc. With End-stage Age-related Macular Degeneration NCT01757132 VisionCare Ophthalmic Technologies, Inc.	Open-label, single-group assignment study	The objective of the PAS-01 study is to assess the safety of the intraocular implant as measured by the cumulative incidence of patients who within 5 years after implantation experience persistent vision-impairing corneal edema (corneal edema leading to persistent loss of best corrected distance visual acuity >2 lines from pre-surgery baseline level). The study will test the null hypothesis that the percentage of patients who experience persistent vision-impairing corneal edema is >17% against the alternative that the percentage	August 2010 December 2028 Enrolling subjects by invitation only n=770	At investigative sites participating in the ECD Sub-Group study, corneal endothelial cell density will be measured by noncontact specular microscopy in a subgroup of 150 patients enrolled in the IMT-PAS-01 in the eye scheduled for and implanted with the intraocular telescope through 60 months	NR	Stable severe vision impairment caused by bilateral central scotomas associated with end-stage AMD, retinal findings of geographic atrophy or disciform scar with foveal involvement Visually significant cataract, achieve at least a 5-letter improvement with external telescope Have adequate peripheral vision in the eye not scheduled for surgery	Stargardt's macular dystrophy Anterior chamber depth <3.0 mm Presence of corneal guttate Do not meet minimum age and ECD requirements Evidence of CNV or treatment of CNV within the past 6 months, previous intraocular or corneal surgery of any kind in operative eye, including any type of surgery for either refractive or therapeutic purposes Have prior or expected ophthalmic-related surgery within 30 days preceding intraocular telescope surgery History of steroid-responsive rise in IOP, uncontrolled glaucoma, or preoperative IOP >22 mm Hg while on maximum medication History of eye rubbing or an ocular condition that predisposes eye rubbing Myopia >6.0 D hyperopia >4.0 D Axial length <21 mm Narrow angle (i.e., <Schaffer grade 2 cornea stromal or endothelial dystrophies,

Table C-30. Ongoing clinical trial of implantable miniature telescope (continued)

Clinicaltrials.gov Title Clinicaltrials.gov Identifier Sponsor	Study Design	Purpose	Start Date Expected Completion Date Estimated Enrollment	Primary Outcomes	Secondary Outcomes	Eye-specific Inclusion Criteria	Eye-specific Exclusion Criteria
		is <17%. The null hypothesis will be rejected if the upper bound of the two-sided 95% confidence integral for the observed percentage is <17%.					including guttate inflammatory ocular disease) Zonular weakness/instability of crystalline lens, or pseudoexfoliation, diabetic retinopathy Untreated retinal tears Retinal vascular disease Optic nerve disease History of retinal detachment Intraocular tumor RP

AMD=age-related macular degeneration; CE=Conformité Européenne; CNV=choroidal neovascularization; D=diopter; ECD=endothelial cell density; logMAR=logarithm of the minimum angle of resolution; IOP=intraocular pressure; NR=not reported; RP=retinitis pigmentosa