Table C-29. Ongoing clinical trials of IRIS (2 studies)

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
Extended Pilot Study to Evaluate Pattern Recognition with a Chronic Retinal Implant System (IRIS) NCT00427180 Intelligent Medical Implants GmbH	Open-label, non-randomized, inter-ventional, single-group assignment study	To investigate whether blind subjects that fulfill the patient criteria provided with a retinal implant can differentiate between simple patterns like horizontal bar, vertical bar, and cross.	December 2006 December 2010 Recruitment status unknown; record last updated March 2010 n=20	Investigate whether blind subjects that fulfill the patient criteria provided with a retinal implant are able to differentiate between simple patterns, such as horizontal bar, vertical bar, and cross, through 18 months	Further evaluation of stimulation parameters Light localization with use of camera Safety Verification of stimulation parameters through 18 months	RP, choroideremia, or rod-cone dystrophy Visual field less than 40 degrees (if measurable) Visual acuity not better than (1/50), (logMAR≥1.7) Visual function stable for a duration of at least 1 year (according to subject statement) Normal eye pressure (9–21 mm Hg) Bulbus length (AP) between 21 and 25 mm	NR
Restoring Vision with the Intelligent Retinal Implant System (IRIS V1) in Patients with Retinal Dystrophy (Title in France: Compensation of Vision with the Intelligent Retinal Implant System [IRIS V1] in Patients with Retinal Dystrophy) NCT01864486 Pixium Vision SA	Open-label, single-group assignment interventional study	To evaluate the safety and effectiveness of the Intelligent Retinal Implants System (IRIS V1)	April 2013 June 2017 (estimated primary completion; full completion date NR) Recruiting patients n=20	Number of adverse events as a measure of safety and tolerability through 18 months after implantation All subjects will undergo ophthalmological examinations in predefined intervals after implantation, including funduscopy, slit lamp examination, and optical coherence tomography. All adverse events	Probable benefit through 18 months after implantation A series of vision test including grating visual acuity, light localization, and contrast sensitivity will be performed before and after implantation of the device.	Has a confirmed diagnosis of RP, choroideremia, or cone-rod dystrophy Has a visual acuity of logMAR 2.3 or worse in both the eyes as determined by a square grating scale Has functional ganglion cells and optic nerve activity Has a memory of former useful form vision Has AP eye dimensions that are appropriate with the dimensions of the implant (In Germany: Has an AP eye dimension between 20.5 and 25 mm)	Has a history of severe glaucoma, uveitis, optic neuropathy, or any confirmed damage to the optic nerve and/or visual cortex Has any disease (other than study-allowed diseases) or condition that affects retinal function of the study eye (e.g., central retinal artery/vein occlusion, end-stage diabetic retinopathy, current or prior retinal detachment, infectious or inflammatory retinal disease) Has any disease or condition that prevents adequate visualization of the retina of the study eye, including corneal degeneration that

Table C-29. Ongoing clinical trials of IRIS (2 studies) (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
				are recorded and analyzed.			cannot be resolved before implantation Has any disease or condition of the anterior segment of the study eye that prevents adequate physical examination (e.g., ocular trauma) Has severe nystagmus Has any ocular condition that leads to eye rubbing Presents with hypotony in the study eye Has active cancer or a history of intraocular, optic nerve, or brain cancer and metastasis In Germany: chronic inflammation of the skin in the area of the eye (e.g., dermatitis, rosacea, infection of the skin, herpes zoster) Chronic inflammation in the area of the eye (e.g., herpes of cornea and/or conjunctiva, recurrent blepharoconjunc-tivitis, hordeolum, chalazion)

AP=anterior-posterior; logMAR=logarithm of minimum angle of resolution; NR=not reported; RP retinitis pigmentosa