Table C-31. Ongoing clinical trial of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant

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**
Photoreceptor Structure in A Phase 2 Study of Encapsulated Human NTC-201 Cell Implants Releasing Ciliary Neurotrophic Factor (CNTF) for Participants with Retinitis Pigmentosa Using Rates of Change in Cone Spacing and Density NCT01530659 Neurotech Pharmaceuticals Collaborator: University of California, San Francisco	Triple-masked (patients, investigator, and outcome assessor) single-group assignment study	A single-site clinical trial for participants who have early stage RP or Usher syndrome (type 2 or 3).	January 2012 August 2019 Recruiting patients n=30	Cone photoreceptor preservation through 24 months after implantation, evaluation of the changes (if present) in cone photoreceptor preservation in the CNTF-treated eye vs. the sham eye as measured by AOSLO	Change(s) in ocular function through 30 months after implantation Change(s) in visual acuity and change in perimetry assessed by: BCVA, changes in visual field using perimetry Changes in the outer nuclear layer thickness as measure by sdOCT Changes in full-field ERG from baseline through 24 months after implantation The presence of peri-implant fibrosis that blocks the visual axis or affects the lens or retina Adverse events affecting ocular function which are thought to be potentially related to the implant	Participant must have a diagnosis of RP or Usher syndrome type 2 or 3 (without profound deafness or cochlear implants) BCVA must be no worse than 20/63 (at least 59 letters) Participants must have clear natural lenses Participants must have less than 6 diopters myopia Participants must have reproducible baseline AOSLO image Participants must have interocular symmetry of disease severity Participant's clinical diagnosis must be consistent with retinal degeneration in the set of RP dystrophies	Participant who has any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 3, or a nuclear opacity > standard 3; or participant is pseudophakic or aphakic Participant has history of corneal opacification or lack of optical clarity Participant has undergone LASIK surgery or other refractive surgery for either eye Participant has nystagmus Participant has greater than 6 diopters myopia Participant has cystoid macular edema with cysts present within 4 degrees of the foveal center that prevent acquisition of at least 7 regions of interest with clear images of cone photoreceptors Participant has fewer than 7 regions of interest present on baseline AOSLO image montages Participant with a history of ocular herpes zoster Participant in whom, as an infant, amblyopia was diagnosed and treated

Table C-31. Ongoing clinical trial of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (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
					Toxicity through 30 months after implantation Safety will be evaluated by the presence or absence of local and/or systemic toxicities.		

AOSLO=adaptive optics scanning laser ophthalmoscopy; BCVA=best corrected visual acuity; CNTF=ciliary neurotrophic factor; ERG=electroretinography; EVA=Electronic Visual Acuity; NEI-VFQ-25: National Eye Institute Visual Function Questionnaire 25 item; OCT=optical coherence tomography; sdOCT=spectral domain optical coherence tomography; RP=retinitis pigmentosa