A Study of AAV5-hRKp.RPGR for the Treatment of Japanese Participants With X-linked Retinitis Pigmentosa

NCT05926583

Status	RECRUITING
Phase	Phase 3
Sponsor	Janssen Pharmaceutical K.K.
Enrollment	4 participants

Key Eligibility Criteria

Inclusion (4)

- Participants who are Japanese male or female aged 5 years or older
- Participants diagnosed as X-linked retinitis pigmentosa (XLRP) (generalized rod-cone dystrophy) associated with pathogenic or likely pathogenic variants in the retinitis pigmentosa guanosine triphosphatase regulator(RPGR) gene
- Has evidence of preserved retinal function as defined by a mean retinal sensitivity of greater than or equal to (\>=) 2 decibel (dB) by Octopus static perimetry and evidence of preserved outer retinal structure (namely the presence of discernible ellipsoid zone) as determined by spectral domain-optical coherence tomography (SD-OCT) in both eyes
- Otherwise, healthy participant on the basis of clinical laboratory tests performed at screening. If the results of the serum chemistry panel or hematology outside the normal reference ranges, the participant may be included only if the investigator judges the abnormalities or deviations from normal to be not clinically significant or to be appropriate and reasonable for the population under study. This determination must be recorded in the participant's source documents and initialed by the investigator

Exclusion (3)

- Has had ocular surgery within 3 months prior to screening or is anticipated to require ocular surgery within 6 months after the AAV5-hRKp.RPGR administration
- Is unable to perform the imaging assessments as required (for example: reliable static perimetry \[reliability factor less than or equal to {\<=}19\], optical coherence tomography \[OCT\], or fundus autofluorescence \[FAF\]).
- Any investigational ocular treatment or any other ocular treatment that could confound the interpretation of the efficacy results or affect participant compliance with the visit schedule

Locations (1 total)

National Hospital Organization Tokyo Medical Center, Meguro-ku, Japan