

A Repeat-Dose, Open-Label, Two Arm Safety and Efficacy Study of Two Doses of VP-001 Administered Intravitreally in Participants With Confirmed PRPF31 Mutation-Associated Retinal Dystrophy, Including Participants Previously Treated With VP001

NCT06852963

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	PYC Therapeutics
Enrollment	16 participants

Key Eligibility Criteria

Inclusion (8)

- Male or female sex; ≥18 years of age at Day 1/Baseline (Visit 2)
- May have been previously enrolled in PLATYPUS Part B (Protocol #VP001-CL101) or WALLABY (Protocol #VP001-CL102) study. At Screening Visit in this study, participants must have completed at least 8 weeks after last study agent administration in PLATYPUS Part B (Protocol #VP001-CL101) or WALLABY (Protocol # VP001-CL102) study
- Have a confirmed clinical diagnosis of Retinitis Pigmentosa.
- Have a confirmed genetic diagnosis of Retinitis Pigmentosa secondary to mutation in the PRPF31 gene.
- For participants not previously enrolled in VP001-CL101 or VP001-CL102 studies: Meet all of the following for visual function in the study eye at the Screening Visit:
... and 3 more (see full listing online)

Exclusion (8)

- Have any uncontrolled systemic disease that, in the opinion of the Investigator, would preclude participation in the study that include but are not limited to infection, uncontrolled elevated blood pressure, cardiovascular disease, or glycemic control issues, or any other medical condition that may put the participant at risk due to study procedures.
- Known mutations in genes that cause autosomal dominant RP, X-linked RP, or presence of biallelic mutations in autosomal recessive RP/retinal dystrophy genes other than PRPF31 mutations.
- Have used anti-VEGF agents within 2 months or corticosteroid injections within the last 3 months.
- Have had Ozurdex® implants placed within 3 months or Retisert® or Iluvien® implants placed within 3 years prior to Baseline (Visit 2).
- Within 3 months prior to Baseline (Visit 2), have undergone any vitreoretinal surgery or any other ocular surgery
... and 3 more (see full listing online)

Locations (6 total)

University of Florida College of Medicine, Jacksonville, Florida, United States
Bascom Palmer Eye Institute - University of Miami, Miami, Florida, United States
Kellogg Eye Center - University of Michigan, Ann Arbor, Michigan, United States
... and 3 more locations

<https://clinicaltrials.gov/study/NCT06852963>

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