

A Phase 1/2, First-in-Human Dose Escalation/Expansion Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of a Subretinal Injection of SB-007 in Subjects With Stargardt Disease (STGD1)

NCT06942572

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Splice Bio
Enrollment	57 participants

Key Eligibility Criteria

Inclusion (14)

- To be eligible for study participation, subjects must meet the following criteria:
 - Provide written consent. Subjects under legal age will also provide informed assent according to guidelines set forth by the same.
 - Are male or female adolescents and adults, aged as follows:
 - In Part A, subjects will be e18 to d65* years (inclusive)
 - In Part B, subject age is planned as e12 to d65* years (inclusive) *Subjects aged \>65 years may be eligible in Parts A and B, following discussion with, and approval by, the Medical Monitor.
- ... and 9 more (see full listing online)

Exclusion (13)

- Subjects must be excluded from participating in the study if they:
 - Have had any intraocular surgery (including cataract surgery) or thermal laser within 90 days of the Screening Visit or planned intraocular surgery (including cataract surgery) or thermal laser during the period of the study, in the study eye.
 - Have had any major surgical procedure within 30 days of the Screening Visit or planned or anticipated major surgery during the period of the study.
 - Have two pathogenic or likely pathogenic variants in IRD genes (other than ABCA4) or a single pathogenic or likely pathogenic variant in autosomal dominant or X-linked IRD genes.
 - Have a history of amblyopia in the study eye.
- ... and 8 more (see full listing online)

Locations (5 total)

UCHealth Sue Anschutz-Rodgers Eye Center,, Aurora, Colorado, United States
Bascom Palmer Eye Institute, Miami, Florida, United States
Massachusetts Eye and Ear Infirmary, Boston, Massachusetts, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT06942572>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).