

# Safety of the Suprachoroidal Injection Procedure Utilizing SCS Microinjector<sup>®</sup> across Three Retinal Disorders

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1. Clearside Biomedical, Inc.

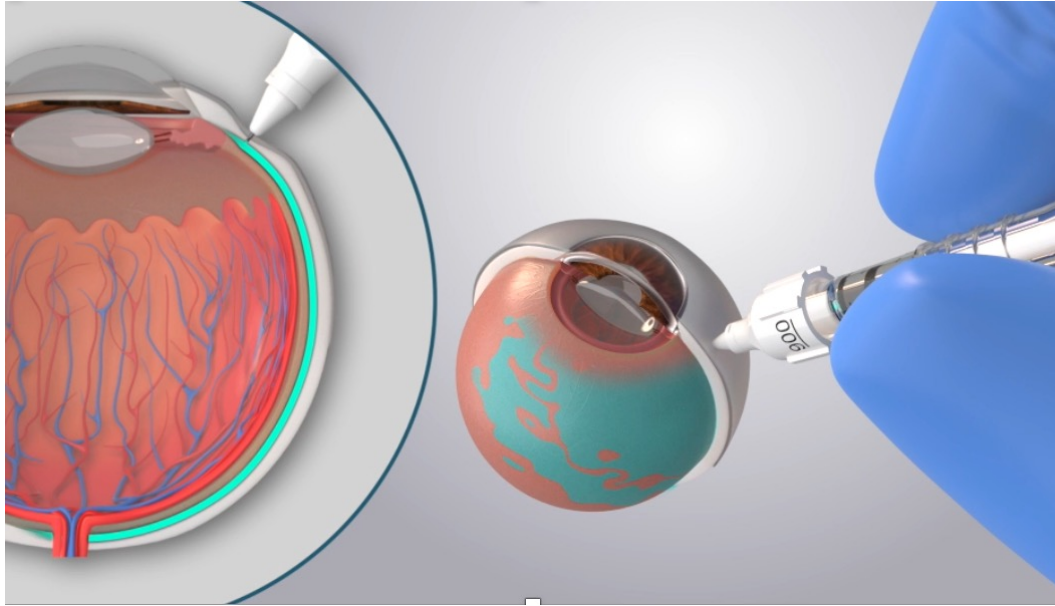


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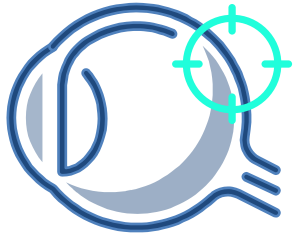
# Financial Disclosures

- MM: Clearside Biomedical, Allergan, Alimera, Regeneron, Genentech, Novartis, Spark - Consultant; Covalent Medical, US Retina - Equity Owner
- CH: Clearside Biomedical - Employment & Shareholder
- TC: Clearside Biomedical - Employment & Shareholder

*“What are the major safety risks of the suprachoroidal injection procedure?”*



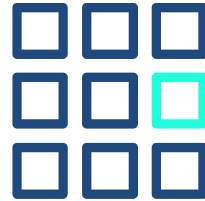
# Advantages of Treating Via the Suprachoroidal Space



## TARGETED

The back of the eye is the location of many irreversible and debilitating visual impairments<sup>1</sup>

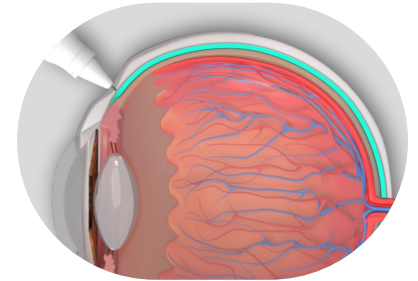
*for efficacy*



## COMPARTMENTALIZED

Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues<sup>2</sup>

*for safety*



## BIOAVAILABLE

Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug<sup>3</sup>

*for durability*



*Footage courtesy of Dr. Allen Hu  
Cumberland Valley Retina Consultants*

# Evaluating SCI data from 8 clinical trials

- SCI data analyzed from 8 clinical trials involving 3 diseases

Noninfectious Uveitis (NIU)	Diabetic Macular Edema (DME)	Retinal Vein Occlusion (RVO)
DOGWOOD (NCT02255032) PEACHTREE (NCT02595398) AZALEA (NCT03097315)	HULK (NCT02949024) TYBEE (NCT03126786)	TANZANITE (NCT02303184) SAPPHIRE (NCT02980874) TOPAZ (NCT03203447)

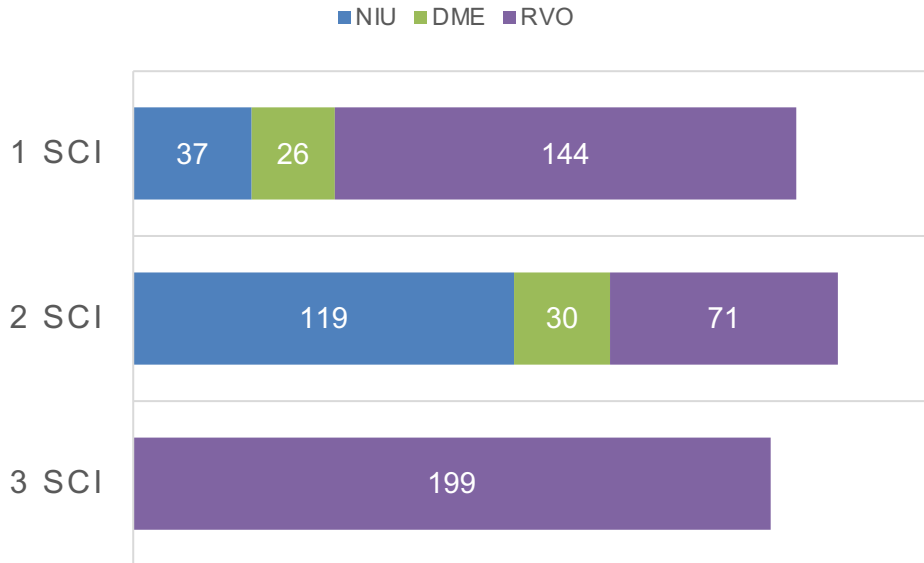
- Events assessed focused on the injection procedure and not on study drug
- Events assessed include rare but serious adverse events (SAEs) reported that are known to occur with intraocular injection

# 626 patients received 1,244 SCIs

## Key Demographics By Disease

	NIU	DME	RVO
Patients, N	156	56	414
Mean age, yrs	51.1	60.7	65.4
Females, n (%)	91 (58.3)	18 (32.1)	188 (45.4)
Whites, n (%)	89 (57.1)	43 (76.8)	278 (67.1)
Phakic, n (%)	79 (50.6)	43 (76.8)	335 (80.9)

## Number of patients receiving SCIs By Disease



# SAEs of interest for suprachoroidal injections

No SAEs involving lens injury, suprachoroidal hemorrhage, endophthalmitis, retinal tears in any patient receiving one or more SCI

SAE	NIU	DME	RVO
Patients, N	156	56	414
Lens Injury, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Suprachoroidal Hemorrhage, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Retinal Tear, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Retinal Detachment, n (%)	1 (0.6) *	0 (0.0)	0 (0.0)
Endophthalmitis, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced Visual Acuity, n (%)	0 (0.0)	0 (0.0)	2 (0.5)**

\*Determined unrelated by masked Investigator, occurred 8 weeks post-SCI in different quadrant than injection.

\*\*Determined unrelated by masked Investigator. One occurring 7 days post 1<sup>st</sup> SCI, another occurring 86 days post 2<sup>nd</sup> SCI.



# Suprachoroidal injections have been well accepted by physicians in clinical trials to date

tvst

Article

## Clinical Characterization of Suprachoroidal Injection Procedure Utilizing a Microinjector across Three Retinal Disorders

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**Conclusions:** Both the user survey and the correlation analysis demonstrated that SC injection is well accepted by physician-investigators, and the two needle lengths accommodate a wide range of anatomic and demographic variables.

# Take Home Message

- In patients with RVO, DME and NIU, there were no atypical safety signals or trends reported during SCIs
  - when analyzing the data cumulatively or when comparing the data between disease states
- Overall, across 8 clinical trials involving NIU, DME and RVO, the safety profile of SCI, either as monotherapy or in conjunction with IVT injection, is comparable to that reported in registration trials involving IVT injections.