Safety of the Suprachoroidal Injection Procedure Utilizing SCS Microinjector® across Three Retinal Disorders

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- SK: Allergan C, Clearside (this talk) none other, Alimera C, Regeneron G, I CROWD C
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- BK: Clearside Biomedical, Employment & Shareholder
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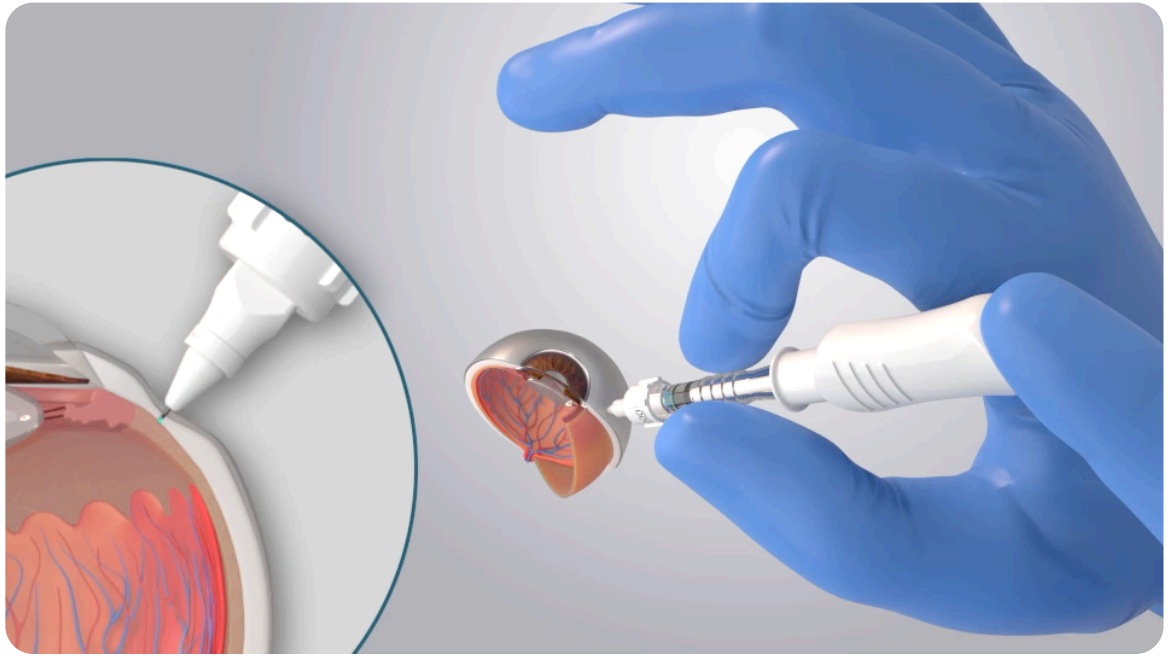
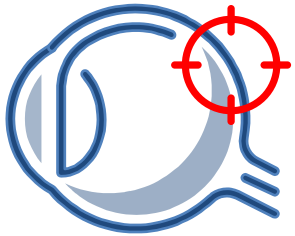
Suprachoroidal Injection (SCI) with the SCS Microinjector®



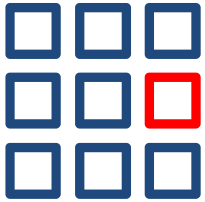
Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

The back of the eye is the location of many irreversible and debilitating visual impairments[1]

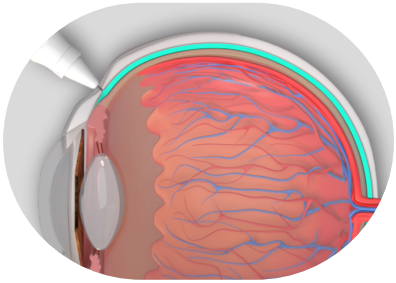
for efficacy



COMPARTMENTALIZED

Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues[2]

for safety



BIOAVAILABLE

Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug[3]

for durability

PK = pharmacokinetic | Sources: 1. Rai UDJ, Young SA, Thrimawithana TR, et al. The suprachoroidal pathway: a new drug delivery route to the back of the eye. Drug Discov Today. 2015;20(4):491-495. 2. Chiang B, Jung JH, Prausnitz MR. The suprachoroidal space as a route of administration to the posterior segment of the eye. Adv Drug Deliv Rev. 2018;126:58-66. 3. Moisseiev E, Loewenstein A, Yiu G. The suprachoroidal space: from potential space to a space with potential. Clin Ophthalmol. 2016;10:173-178.

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Methods

- Safety data collected from datasets from 8 clinical trials and 3 disease states
  - SCI Group: Subjects who received 1+ SCI (4.0 mg CLS-TA) as monotherapy (n=161) or w/ IVT anti-VEGF (n=460)
  - Control: Subjects who received an IVT + sham SCI (n=449)
- Treatment emergent adverse events (TEAES) occurring on the day of SCI were considered temporally related, regardless of whether Investigators reported them as such.

Noninfectious Uveitis	Diabetic Macular Edema	Retinal Vein Occlusion
DOGWOOD PEACHTREE AZALEA	HULK TYBEE	TANZANITE SAPPHIRE TOPAZ

SCI = suprachoroidal injection

Results: Serious Adverse Events (SAEs)

SCI Group

- **No SAEs involving lens injury, suprachoroidal hemorrhage, endophthalmitis, retinal tears in any patient receiving 1 or more SCI**
- 3 SAEs of interest, all deemed “not related” by masked investigator
  - NIU: Retinal detachment (n=1)
    - *Occurred 8 weeks post-injection in different quadrant than SCI*
  - RVO: reduced vision (n=2)

Control (IVT + sham SCI)

- In control group: 3 SAEs of interest, all deemed “not related” by masked investigator
  - RVO: retinal detachment, vitreous hemorrhage, endophthalmitis

Results: Treatment Emergent Adverse Events

Both groups: **No serious TEAEs involving the study eye and no cases of lens injury, suprachoroidal hemorrhage, endophthalmitis, retinal tear, or retinal detachment were reported on the day of injection.**

SCI Group: Incidence of Eye Pain or Discomfort, by Disease State		
NIU	DME	RVO
11.3% (n=17)	0% (n=0)	6.0% (n=25)

Control (IVT + sham SCI, RVO and DME)

- 1.6% of subjects experienced a TEAE associated with eye pain or discomfort

SCI = suprachoroidal injection;

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 96	
	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)	EYLEA (N=1824)	Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%	27%	30%
Eye pain	9%	9%	10%	10%
Cataract	7%	7%	13%	10%

Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

Adverse Reactions	CRVO		BRVO	
	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival he				
Intraocular pres				
Corneal epitheli				

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 100	
	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium	5%	3%	7%	5%

Conclusion

The safety profile of SCIs is comparable to IVT injections alone for events occurring at or after the procedures.

- Across 8 clinical trials involving NIU, DME and RVO, either as monotherapy or in conjunction with IVT injection