SILKTECH
Silk-Derived Protein-4 (SDP-4)
Biotherapeutic for Treating Dry Eye

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Designed to treat the signs & symptoms of DED

- Inhibit inflammation & physically improve tear film stability

Novel biologic drug with dual mechanism of action

- **NF-κB inhibitor** to reduce pro-inflammatory mediators of DED
- **Mucin replacement** to enhance formulation spreading & wetting
Dry Eye Disease (DED) affects 340MM

- 15 million in US & 40 million undiagnosed
- Impacts multiple ocular surface tissues

Targeted areas for innovation impact

- Enhance tear film stability with added protein
- Increase anti-inflammatory effectiveness
NF-κB activity affects multiple tissues

- Corneal & Conjunctival tissues
- Meibomian & Lacrimal glands

Drives pro-inflammatory mediators

- Positive feedback signaling
- Drives immune cell recruitment
NF-κB Driven DED Inflammation

NF-κB activity affects multiple tissues
• Corneal & Conjunctival tissues
• Meibomian & Lacrimal glands

Drives pro-inflammatory mediators
• Positive feedback signaling
• Drives immune cell recruitment
Intracellular IκB kinase inhibitor

- Actively absorbed by ocular surface cell types
- Inhibits inflammatory gene transcription

Pre-clinical study results

- 8-fold reduction in MMP-9 presence (*in vivo)*
- 50% - 70% reduced gene transcription (*in vitro*)
- 80% reduced immunological response (*in vitro*)

* Abdel-Naby et al., PLOS | ONE, 2017
SDP-4 inhibits NF-κB activity

- Dose dependent, 20-fold reduction
- Maximal response at 1% wt./wt.

Negligible toxicity profile

- SDP-4 well-tolerated in vivo
- Non-immunogenic
- Rapid blood clearance ($t_{1/2} < 30$ min.)
SDP-4 has mucin-like spreading & wetting ability
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<tr>
<th>Wax Surface</th>
<th>Saline</th>
<th>Saline + 1% SDP-4</th>
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SDP-4 has mucin-like spreading & wetting ability
Silk fibroin protein derivative

- Highly soluble, intrinsically disordered
- Repeating peptide sequence structure

Patent protection through 2037
Unique Formulation Properties

- Aqueous, transparent & preservative free
- Highly stable at room temperature
- Inexpensive to produce
- Designed to limit potential side effects
Product Development Timeline

2018

GMP Manufacturing

Pre-Clinical Studies

2019

SDP-4 Sterile Topical Ophthalmic Solution

IND Submission: Q1 ’19

Phase IIIB Clinical Trial

2020

EOP2: Q1 ’20
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