ST-100 Repairs Corneal Nerve Bed in Dry Eye Patients

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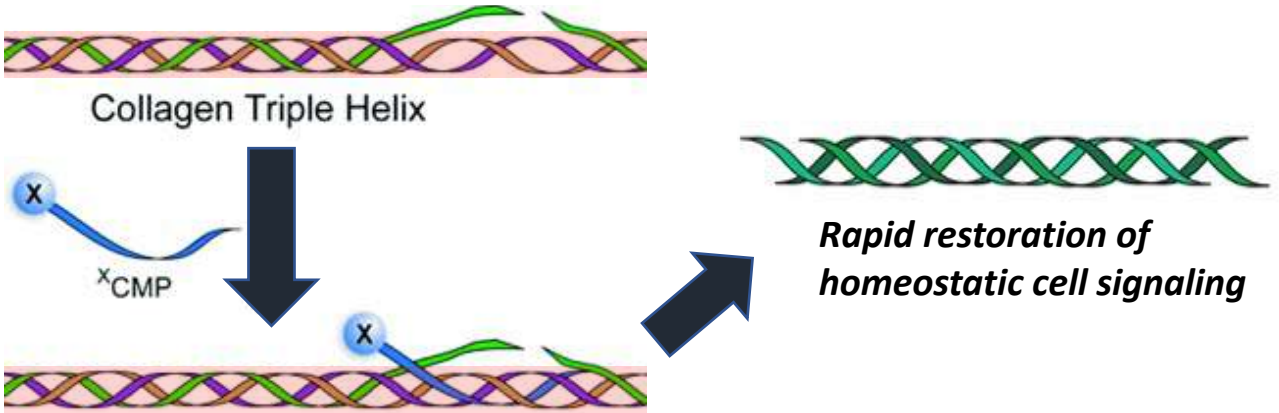
Stuart Therapeutics is Building a Leading Therapeutic Development Organization in Ophthalmology

- A **clinical stage company**, developing a **unique, patented platform technology (PolyCol™)**
- **Successful First In Human Phase 2 clinical trial** in Dry Eye Disease
- **Groundbreaking neuroprotection research** results, with a second drug candidate for glaucoma/intraretinal neuroprotection
- **Additional programs** in the pre-clinical stage, including Dry AMD, Myopia and several ocular surface indications

Damaged Helical Collagen is a *New Therapeutic Target* – with a Powerful Effect on Tissue Health and Inflammation

***PolyCol™*: Collagen Mimetic Peptide (CMP) Platform That Restores the ECM[1]**

Damaged/Remodeling Helical Collagen



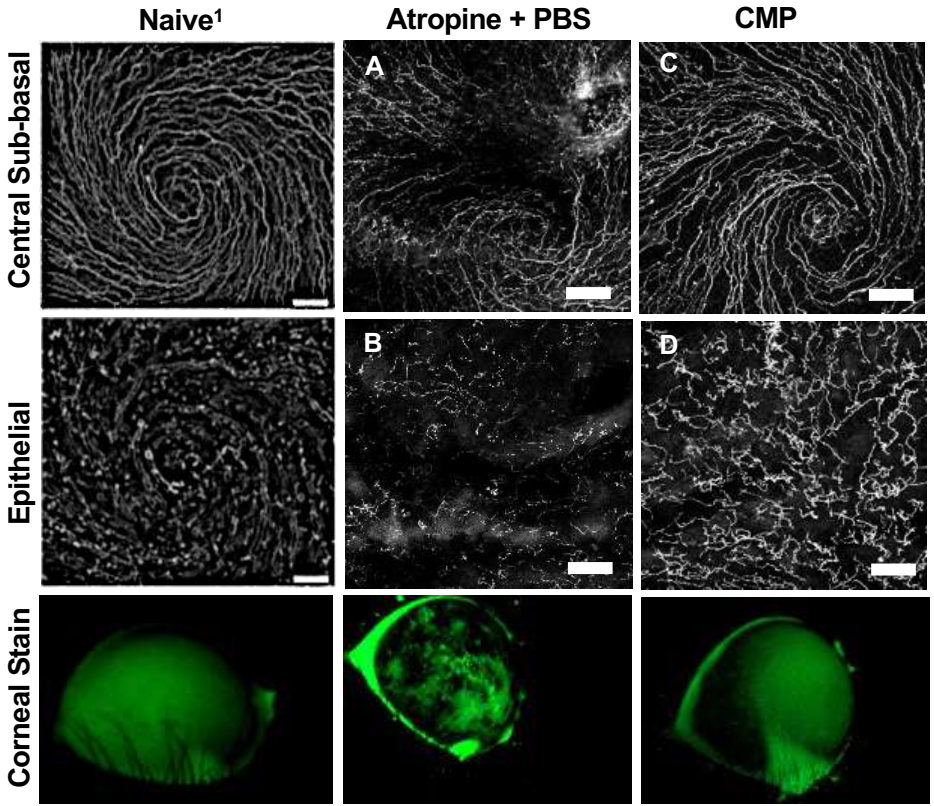
Rapid restoration of homeostatic cell signaling

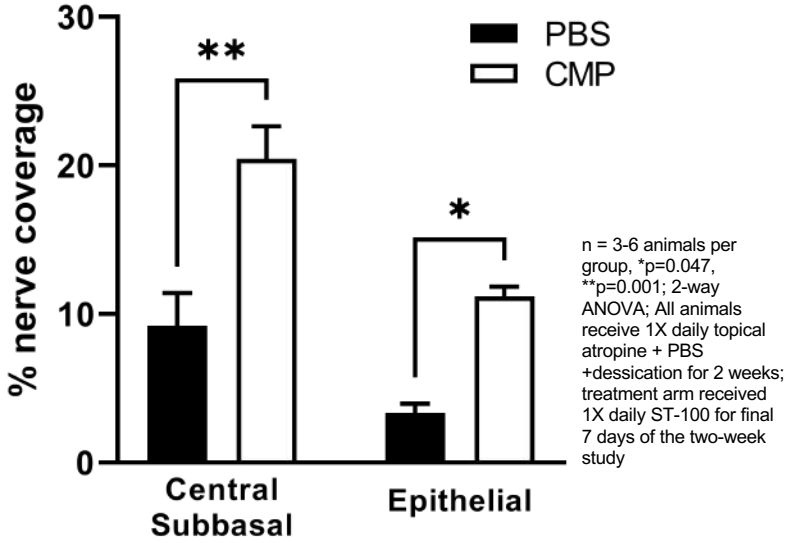
CMP <u>repairs</u> damaged helices, MOA is selective

Stuart is the first company to develop CMPs for therapeutic applications; restoration of the ECM yields homeostatic cell activity

[1] ECM: Extracellular Matrix

Repair of the Corneal Nerve Bed Restores the Ocular Surface

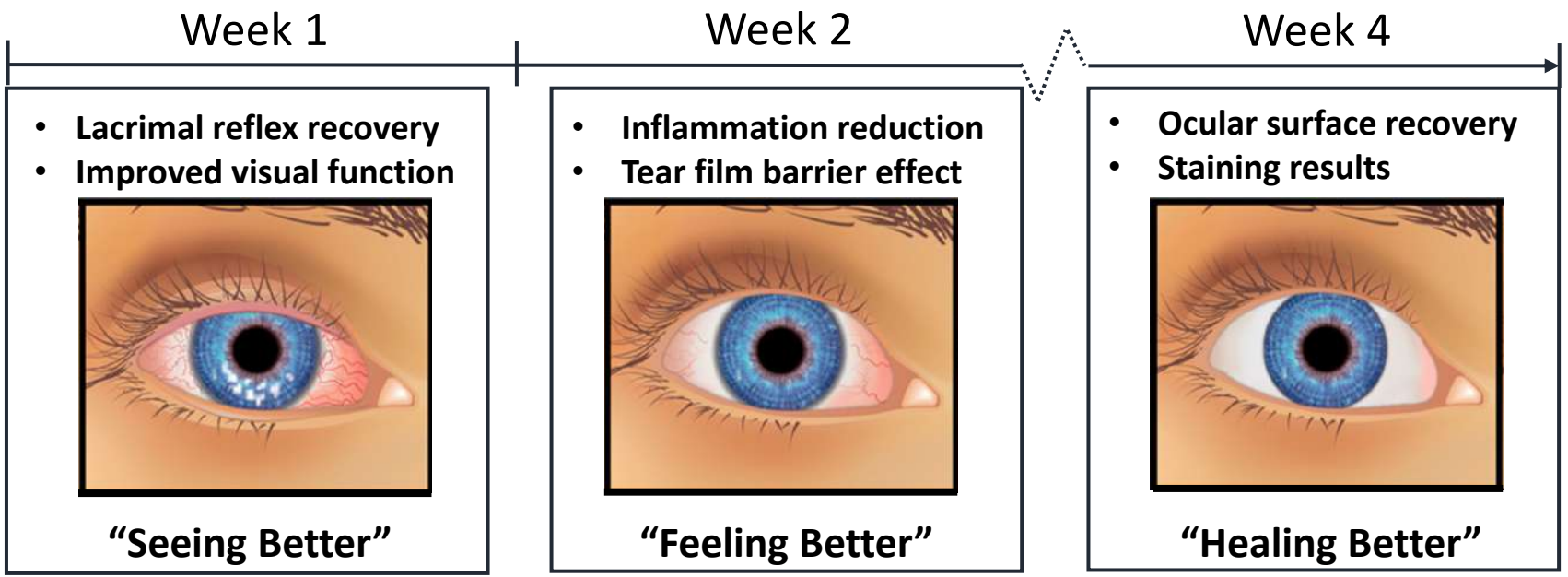




n = 3-6 animals per group, *p=0.047, **p=0.001; 2-way ANOVA; All animals receive 1X daily topical atropine + PBS +dessication for 2 weeks; treatment arm received 1X daily ST-100 for final 7 days of the two-week study

Mouse Corneal nerve coverage following dessication regimen. Representative confocal micrographs of β(III)Tubulin-stained central sub-basal (**A**) and epithelial (**B**) nerve beds after atropine + PBS (vehicle) ***vs.*** atropine + CMP treatment (**C, D**). Scale = 50 µm. Percentage β(III)Tubulin nerve coverage after atropine + PBS and atropine + CMP.

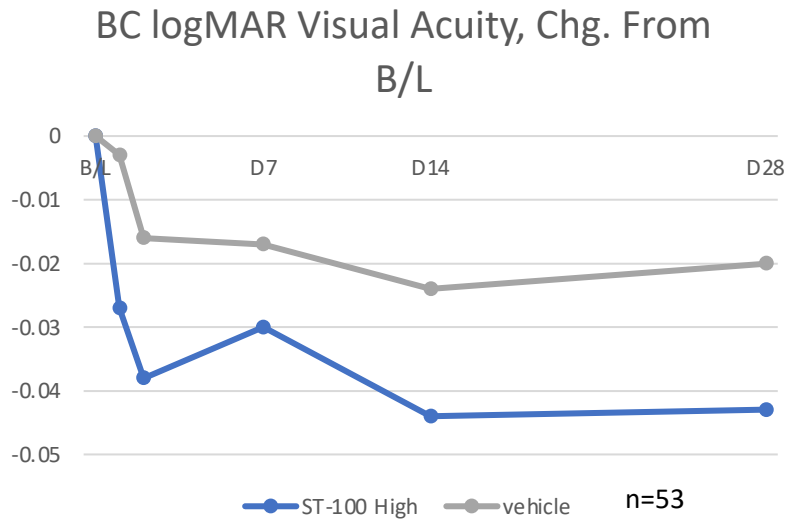
Corneal Nerve Repair Restores Basal Tear Function, Resulting in Rapid Resolution of Dry Eye Disease



ST-100’s 28-Day Phase 2 trial:
all endpoints with pre-CAE[1] significance and zero serious adverse events

[1]CAE: Controlled Adverse Environment Chamber

Persistent Visual Function Improvements Beginning Day 2 Suggest Lacrimal Functional Unit (LFU) Recovery



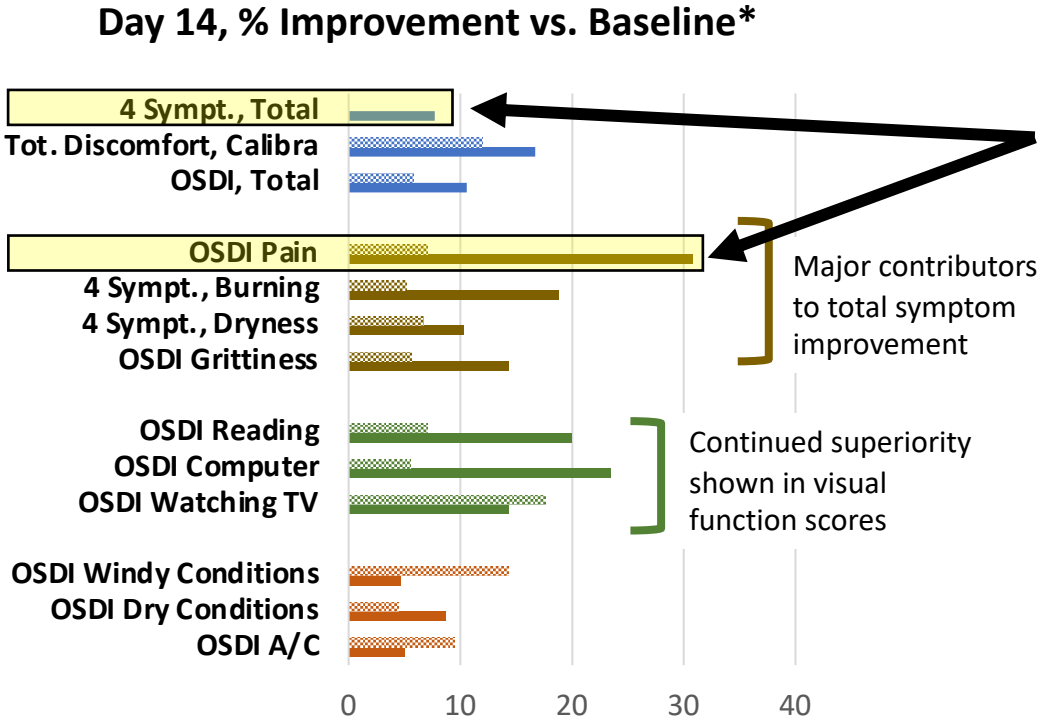
”Seeing Better”

ITT Population Endpoints:

BC logMAR, Day 2: *p = 0.0055*
Blurred Vision*, Day 3: *p = 0.0097*

A subset of ST-100 patients achieved between 2 and 3 lines of visual function improvement by D14, vs. zero in the vehicle group

Inflammation Reduction + Tear Film Barrier Effect: Day 14 Symptom Trends for All Major Scoring Methods



”Feeling Better”

ITT Population Endpoints:

4 Symptom, Total D14, *p=0.0332*

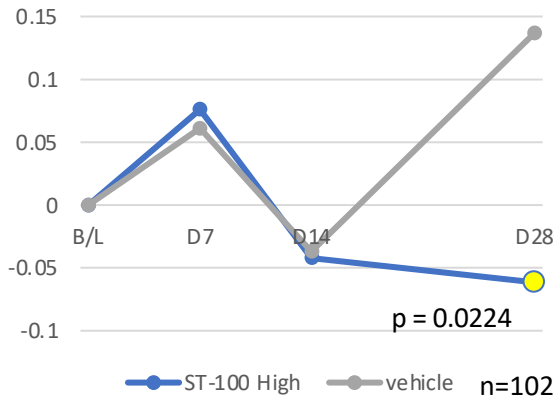
OSDI Pain, D14, *p=0.0137*

All measurements and endpoints pre-CAE, bold bars are ST-100 High, and shaded bars are vehicle

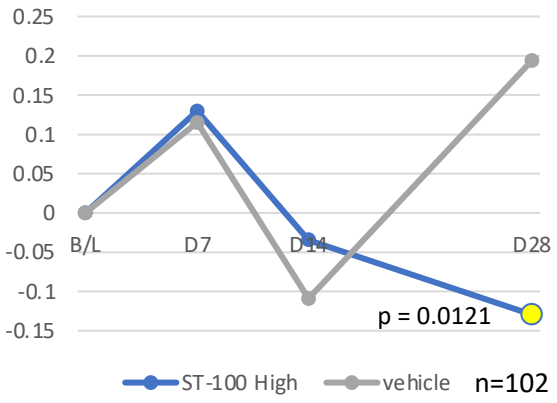
Consistent with a Nerve Repair MOA, Staining Results Followed Visual Acuity and Symptom Relief - Day 28

”Healing Better”

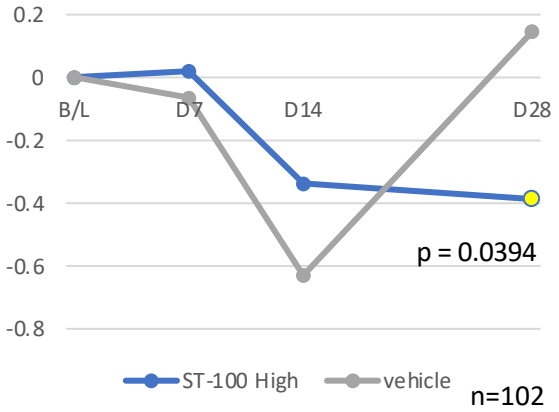
Temporal Conj. FL Stain, Chg. From B/L



Total Conj. FL Stain, Chg. From B/L



Total Eye FL Stain, Chg. From B/L

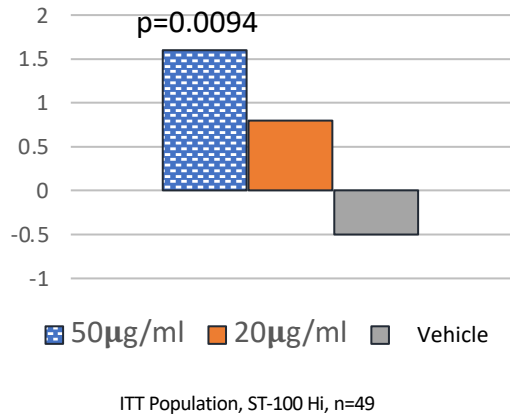


The prolonged effect of nerve repair and inflammation reduction supports ocular surface healing and staining reduction, beginning in the conjunctiva

All measurements and endpoints pre-CAE, study and fellow eyes combined, data are change from baseline

Homeostatic Recovery of Basal Tears Resulted in Day 28 Schirmer's Responder Rate Endpoint

Mean Change from B/L in Schirmer's Score, Day 28, *mm*



ITT Population, ST-100 Hi, n=49

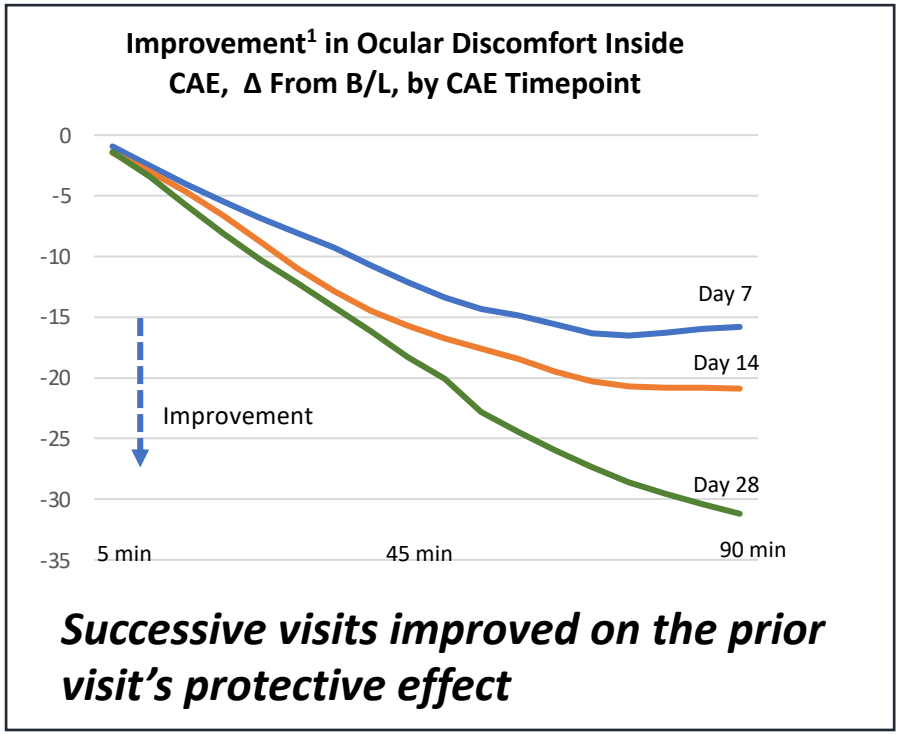
Schirmer's Responder Rate:
Single approvable endpoint[1] without using CAE chamber

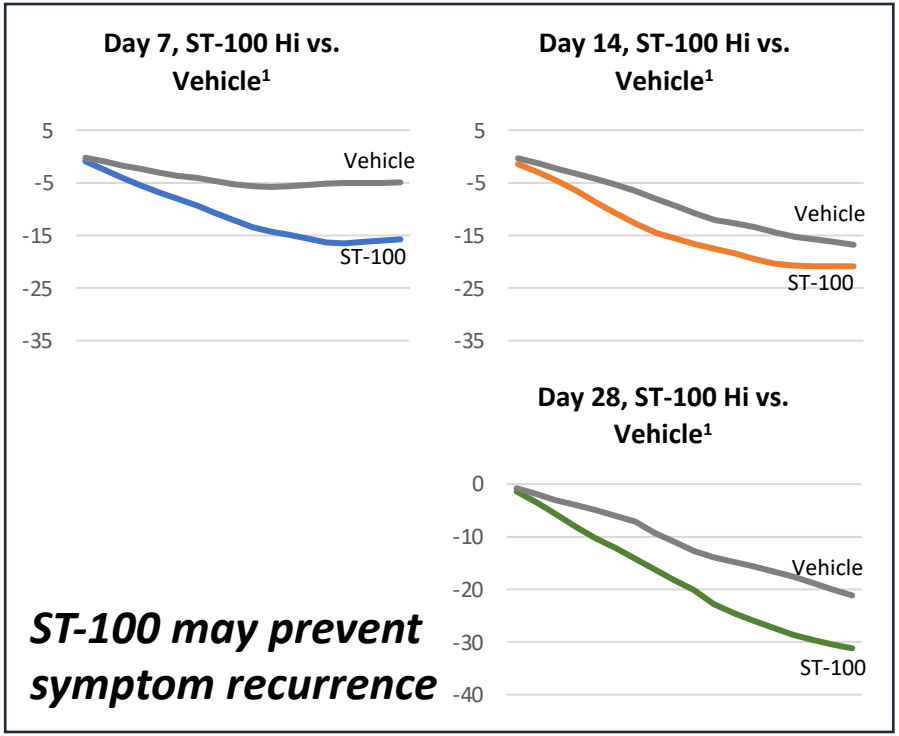
	ST-100	Cequa®	Restasis®
Trial Duration	***28 days***	90 days	180 days
Patients (Drug)	***49***	152	405
Difference (95% CI)	***12.2%***	8.2%	10%
p-value vs. vehicle	***0.0266***	<0.01	Not Reported

Lacrimal functional unit (LFU) and basal tear-based recovery in dry eye patients is consistent with pre-clinical corneal nerve repair

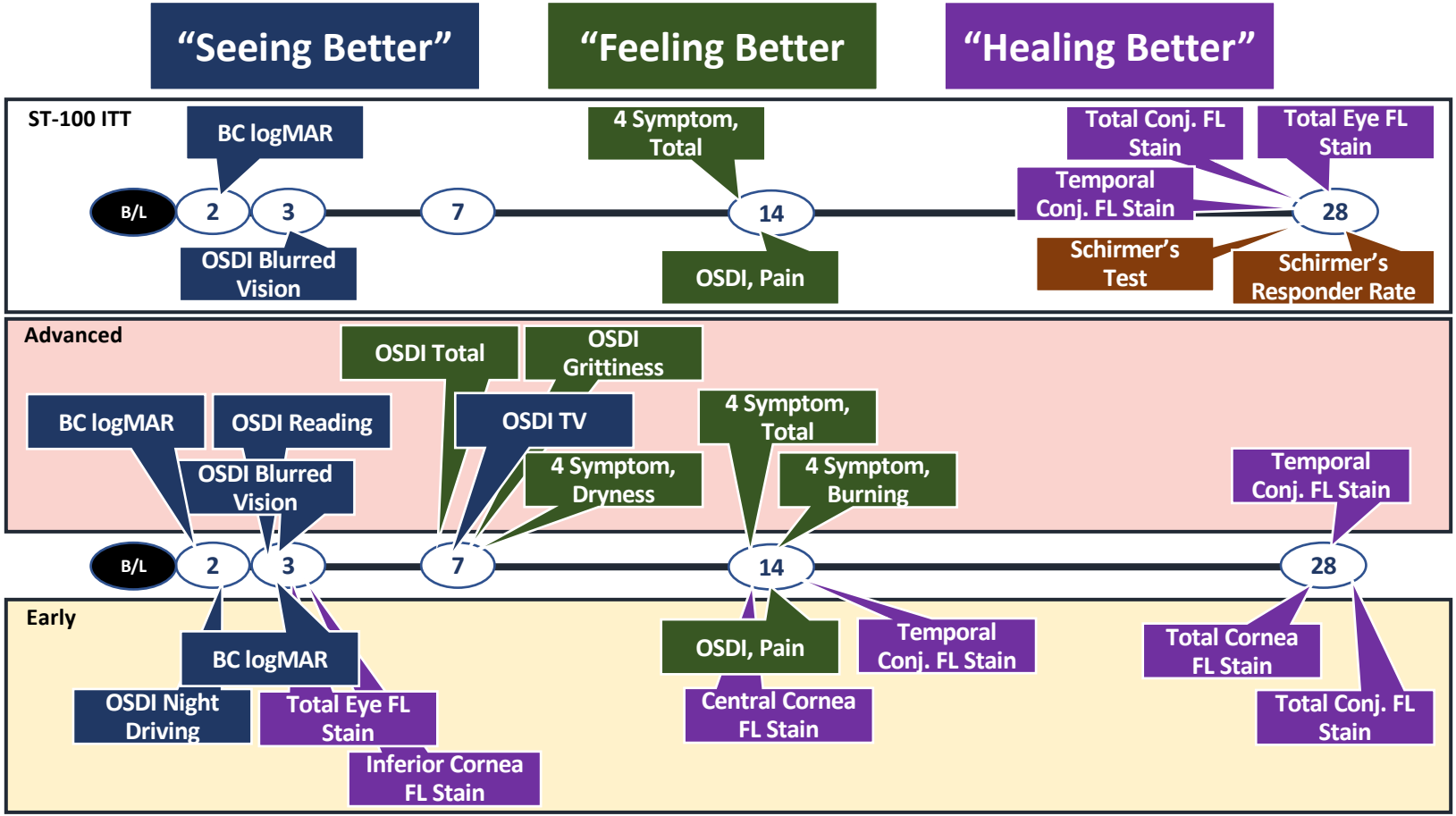
All measurements and endpoints pre-CAE
[1]Source: Cequa® and Restasis® labels and published results

During CAE Sessions, Patients Showed Potential Protective Effect of ST-100 Under Stress[1]





[1] Area under the curve analysis of Total Ocular Discomfort (Calibra), change from baseline, at each 5-minute timepoint during 90-minute Controlled Adverse Environment chamber sessions, Day 7, 14 & 28; ITT Population; Calibra Ocular Discomfort Score Range: 0 - 4



ST-100 significant endpoints for ITT and early-stage and late-stage dry eye patient cohorts

ST-100 is the First Therapeutic to Address in 28 Days Visual Function, Symptoms, Staining, and Tear Production

ST-100 was effective, safe and well tolerated in its Phase 2 Dry Eye trial:

- ✓ **Restoration of full LFU**
- ✓ **Early improved visual function**
- ✓ **Rapid symptom relief**
- ✓ **Total eye stain improvement**
- ✓ **Schirmer's Responder single approvable endpoint**

Thank You

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