BLACK HILLS REGIONAL EYE INSTITUTE

# Clinical Research Trials

## Principal Investigators Include: Stephen Khachikian, MD & Adam Jorgensen, MD

For more information please call Bailey DeBaere at 605-719-3153

| Company & Study name | Study Rationale | Study Candidates & Duration | Current Enrollment |
|---|---|---|---|
| | | | |
| **Cataract**<br>**LEXITAS**<br>**CPN-302**<br>**PI: Khachikian**<br>**SUBI: Jorgensen Bergman** | A Multicenter, Randomized, Double-Masked, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of APP13007 for the Treatment of Inflammation and Pain after Cataract Surgery, Including a Corneal Endothelial Cell Sub-study | Patients with routine unilateral cataract surgery on the day prior to study randomization.<br>~3-7 weeks (Main study)<br>~12-17 weeks (Sub-study) | Open |
| **Glaucoma**<br>**SANTEN**<br>**PI: Jorgensen**<br>**SUBI: Scarborough** | A Phase IIb, Randomized, Double-Masked, Active-Controlled, Parallel-Group, Multicenter Study Assessing the Efficacy and Safety of DE-126 Ophthalmic Solution 0.002% Compared with Timolol Maleate Ophthalmic Solution 0.5% in Subjects with Primary Open Angle Glaucoma or Ocular Hypertension | Patients with Glaucoma Drops twice a day.<br>~3-5 months (~5 visits) | Open |
| **Glaucoma**<br>**ALLERGAN**<br>**PI: Jorgensen**<br>**SUBI: Khachikian** | A Phase 3b, Study to Evaluate the Duration of Effect of Bimatoprost SR in Participants with Open-Angle Glaucoma or Ocular Hypertension | Patients with Glaucoma Bimatoprost SR refers to the biodegradable, sustained-release, preservative-free bimatoprost implant<br>4-years | Open |
| **Glaucoma**<br>**GLAUKOS**<br>**PI: Jorgensen**<br>**SUBI: Khachikian Scarborough** | Prospective, Randomized Phase 3 Study Comparing Two Models of a Travoprost Intraocular Implant to Timolol Maleate Ophthalmic Solutions, USP 0.5%. | Patients with Glaucoma iDose implant 3-years | Ongoing/ Closed |

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| **Dry Eye**<br>**SURFACE PHARM**<br>**C-100-001**<br>**PI: Khachikian**<br>**SUBI:**<br>**Schirber**<br>**Scarborough** | A phase 2, multicenter, randomized, double-masked study to evaluate the safety, tolerability, and efficacy of SURF-100 ophthalmic solution (a mycophenolic acid/betamethasone sodium phosphate combination) in subjects with dry eye disease | Patients with dry eye syndrome<br>Drops twice a day<br>~ 3 months (7 visits) | Open |
| **Sjögren's**<br>**ORA**<br>**SYL1001_V**<br>**PI: Khachikian**<br>**SUBI:**<br>**Schirber**<br>**Bergman** | Tivanisiran for Dry Eye in Subjects with Sjögren's Syndrome (SYL1001_V) Phase 2 Multicenter, randomized (1:1) study with a 14-day, single-masked, Run-In vehicle treatment phase followed by an 85-day, double-masked, active and vehicle-controlled treatment phase in approximately 200 subjects with dry eye associated with Sjogren's Syndrome | Patients with Sjogren's<br>Drops once a day for 2 weeks.<br>3 months (5 visits) | Open |
| **Presbyopia**<br>**ORASIS**<br>**NEAR-1**<br>**PI: Khachikian**<br>**SUBI:**<br>**Schirber**<br>**Scarborough** | Phase 3: A Multi-Center, Double-Masked, Vehicle-Controlled, Evaluation of the Efficacy and Safety of CSF 1 in the Temporary Correction of Presbyopia (the NEAR-1 study: Near Eye-vision Acuity Restoration) | Patients with presbyopia<br>Drop twice a day for 2 weeks.<br>~ 4 weeks (4 visits) | Open |
| | **Contact Bailey DeBaere at 605-719-3153** | | |