Title: Eight-Week Safety and Efficacy of a Novel Ocular Surface Cooling Device for Chronic Ocular Surface Pain: Double-Masked RCT Results

Submitter's E-mail Address: preeyakgupta@gmail.com

Category: CORNEA

Topic: Medical and Surgical Ocular Surface

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Keywords: Chronic ocular surface pain, corneal nerves and dry eye disease

Purpose: To assess short-term (8-week) clinical safety and efficacy outcomes in eyes with chronic ocular surface pain (COSP)that have been treated with a novel topical ocular cooling device targeting the long ciliary nerves of the eye.

Methods: Unilateral treatments with the cooling device were administered to the ocular surface of 31 subjects. Twenty eyes received the interventional treatment and eleven eyes received a sham treatment. Patient reported outcomes were collected weekly (either in person at week 2 and 8 visits or via virtual visit) using the visual analogue scale (VAS),ocular pain assessment survey (OPAS) and chronic ocular pain questionnaire (COP-Q). Clinical exam, evaluation ofAdverse events (AEs), and Cochet-Bonnet corneal sensitivity testing were conducted at baseline, week 2, and week 8.All subjects were followed for eight weeks.

Results: The VAS, OPAS, and COP-Q all trended towards a mean reduction in eye pain from baseline that was greater in the interventional arm vs sham arm. The COP-Q demonstrated a statistically significant reduction in eye pain severity from baseline relative to the sham group at Week 8 in patients screened for peripheral-dominant COSP via an anesthetic challenge (p=0.042). Corneal sensitivity testing statistically significantly improved in the treatment arm by week 8(45.6mm to 50.0mm, p=0.042) and did not improve in the sham arm. No serious AEs were reported. The most commonAEs

were transient mild to moderate conjunctival hyperemia, eye pain, and foreign body sensation immediately post-treatment.

Conclusion: These results suggest that ocular surface treatment using a novel ocular surface cooling device is well tolerated, improves
corneal sensation, and provides relief from COSP through 8-weeks post-treatment.

Authors:
Preeya K. Gupta, MD (Presenting Author); Christopher J. Rapuano, MD, ABO; Sam Garg, MD, ABO; Alice T.Epitropoulos, MD, FACS, ABO; Bonnie An Henderson, MD, ABO; Anat Galor, MD, MPH

Disclosures:
Preeya K. Gupta, MD (Presenting Author): Disclosure Complete
Christopher J. Rapuano, MD, ABO: Disclosure Complete
Sam Garg, MD, ABO: Disclosure Complete
Alice T. Epitropoulos, MD, FACS, ABO: Disclosure Complete
Bonnie An Henderson, MD, ABO: Disclosure Incomplete
Anat Galor, MD, MPH: Disclosure Incomplete