Protocol Synopsis – Public Summary Version

For: NCT06381986

A Clinical Study on the Safety and Efficacy of SHJ002 Sterile Ophthalmic Solution in the Treatment of Corneal Erosion in Patients with Sjogren's Syndrome

Sponsor: Sunhawk Vision Biotech, Inc.

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1. Study Objectives

Primary Objective:
To evaluate the efficacy of SHJ002 ophthalmic solution in reducing corneal fluorescein staining in patients with corneal erosion secondary to Sjogren's Syndrome.
Secondary Objectives:
To assess changes in regional fluorescein staining (iCFS) and patient-reported symptoms using the SANDE questionnaire.

2. Study Design

Design: Multicenter, double-blinded, randomized, vehicle-controlled, parallel-group Phase 2 trial
Participants: Adults ≥18 years with Sjogren's Syndrome and corneal erosion
Randomization: 1:1 ratio to SHJ002 or vehicle group
Treatment: One drop per eye, twice daily for 12 weeks
Sites: Multiple hospitals in Taiwan

3. Endpoints

Primary Endpoint:
Change from Baseline to Week 12 in Total Corneal Fluorescein Staining (NEI Scale, score range 0–15; higher scores indicate more severe staining)
Secondary Endpoints:
- Change in Inferior Corneal Fluorescein Staining (iCFS) Score by NEI Scale (0–3 per region; higher scores = worse outcome)
- Change in Symptom Assessment in Dry Eye (SANDE) score (0–100 scale; higher = worse symptoms)

4. Inclusion / Exclusion Criteria

Key Inclusion:
- Adults ≥18 years
- Diagnosed with Sjogren's Syndrome and corneal erosion
- Negative pregnancy test for women of childbearing potential

Key Exclusion:
- Ocular diseases other than corneal erosion/DED
- Recent ocular surgery
- Conflicting medication use or other interfering conditions

5. Statistical Analysis Overview

Primary Efficacy Analysis:
Mixed Model for Repeated Measures (MMRM) used to analyze change in CFS from baseline, with covariates including treatment, visit, interaction, and baseline score.
Reporting:
Least squares means (LSM), standard error (SE), 95% confidence intervals (CI), and treatment group comparisons with p-values.
Missing Data:
Assumed Missing at Random (MAR); no imputation was needed.