Efficacy Evaluation of a Water-Free Ciclosporin in Dry Eye Disease Patients with underlying Sjögren‘s Syndrome:
A Subgroup Analysis of the SHR8028-301 Trial

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Background:

Sjögren’s syndrome is associated with an immune-mediated aqueous deficient Dry Eye Disease (DED). Due to the underlying immune-based inflammatory component, topical ciclosporin, as an anti-inflammatory immunomodulator, may be an optimal therapeutic option for this patient subgroup.

Methods:

This post-hoc analysis from the randomized, controlled phase 3 clinical study (SHR8028-301[1]) conducted with 206 DED patients in China investigated the treatment effect of a novel water-free ciclosporin, 0.1% ophthalmic solution (brand names: Vevizye® in EU/Vevye®in US) in patients with and without underlying Sjögren’s syndrome. The following endpoints were assessed: change from baseline in total corneal fluorescein staining (tCFS) using the NEI scale and proportion of responders for tCFS (≥3 grades improvement) and change from baseline in conjunctival staining using the Oxford scale. Changes from baseline in tCFS and conjunctival staining were analyzed using an ANCOVA model. The proportion of responders for tCFS (≥3 grades improvement) was analyzed using logistic regression model.

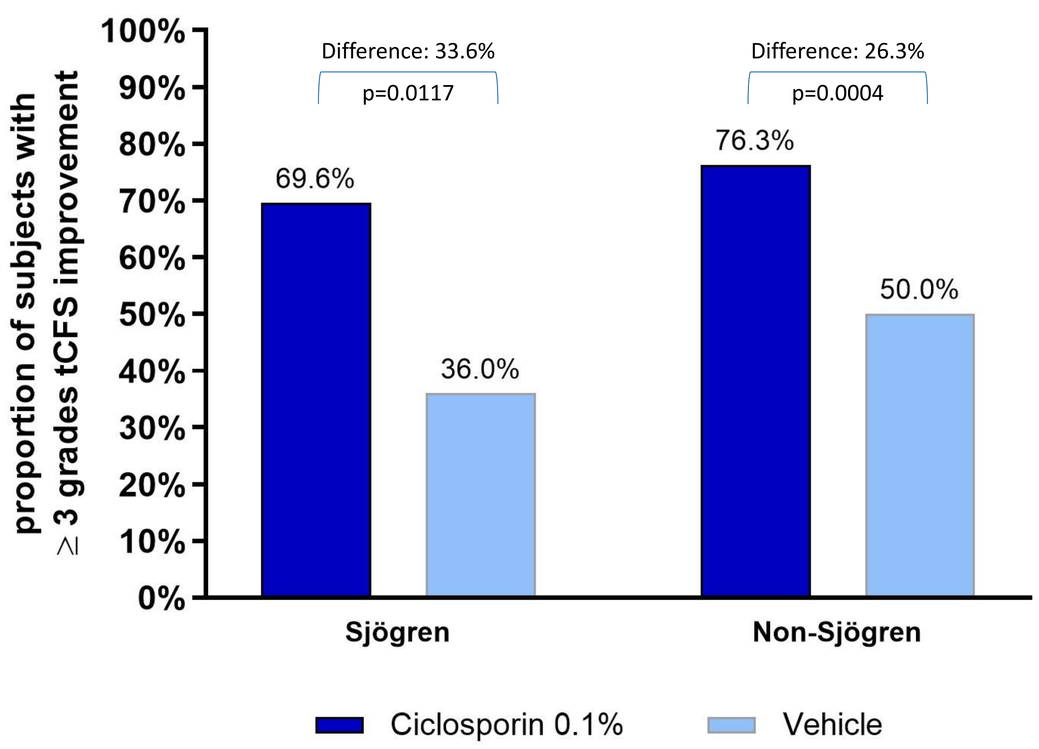
Results:

Population

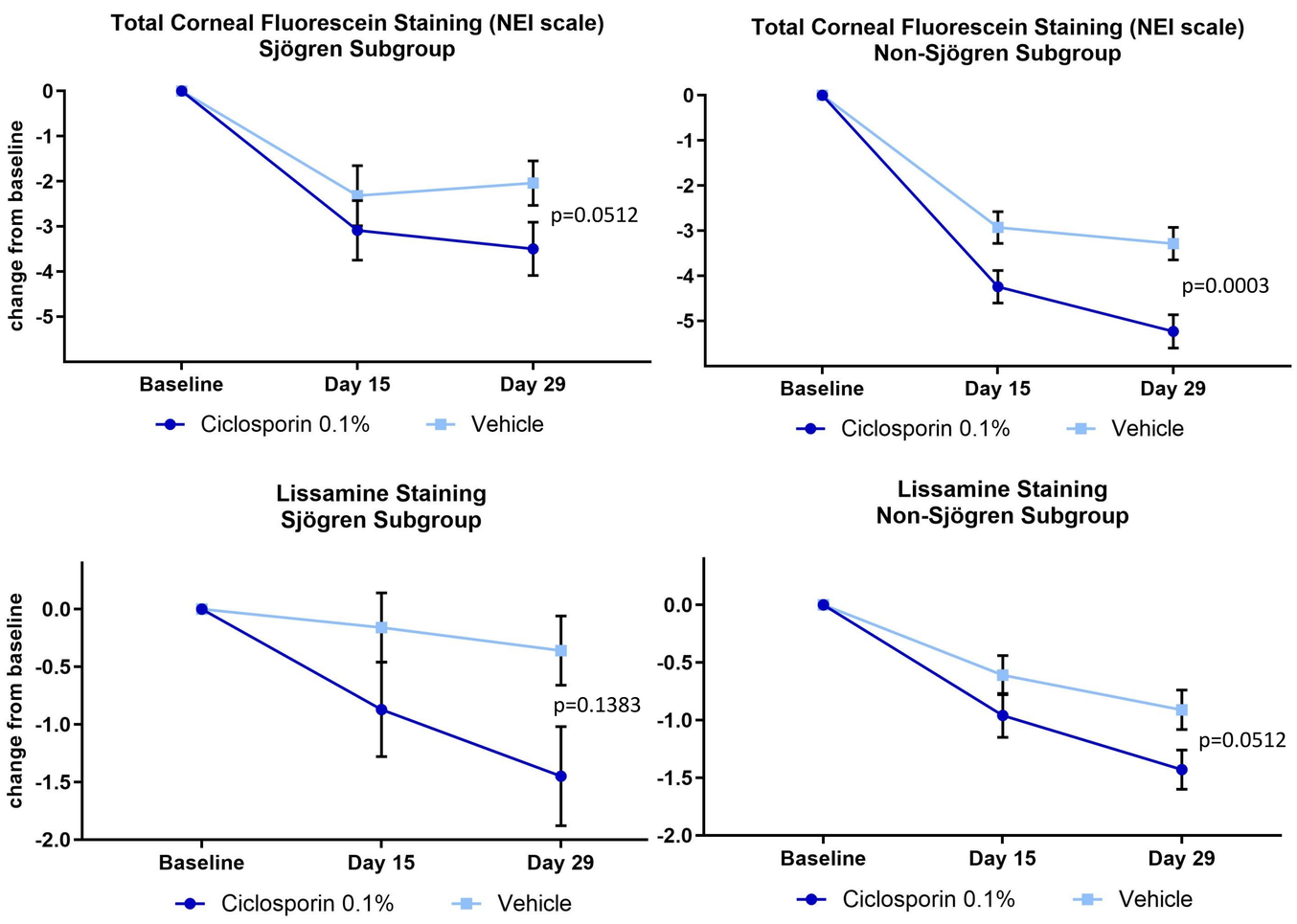
48 patients (23 ciclosporin/25 vehicle) or 23% of all patients reported with systemic Sjögren’s syndrome. These patients were older, had longer disease duration and more severe DED signs compared to patients without underlying Sjögren’s syndrome in this registrational trial.

	Sjögren N= 48	Non-Sjögren N= 158
Female, n [%]	46 [95.8%]	139 [88%]
Age, mean [SD]	54.1 [14.58]	45. 9 [13.61]
Duration of DED, months mean [SD]	95 [80.1]	41 [38.0]
tCFS, mean [SD]	12.8 [1.88]	12.1 [1.79]
Lissamine, mean [SD]	5.9 [2.32]	3.9 [1.97]
Schirmer, mean [SD]	2.9 [2.05]	4.1 [2.62]
Total OSDI, mean [SD]	53.2 [22.82]	48.5[22.56]
Dryness Score (VAS), mean [SD]	75.7 [12.65]	72.2 [12.70]

Proportion of responders for tCFS (≥3 grades improvement)



Change from baseline tCFS and conjunctival staining



Key findings:

- The water-free ciclosporin solution was effective in reducing ocular surface staining in DED patients with underlying Sjögren’s syndrome, reaching significance for the corneal staining responder analysis after 4 weeks of treatment.
- The magnitude of the treatment effect of water-free ciclosporin versus vehicle was comparable across both subgroups
- Sjögren’s patients tend to show a smaller response to vehicle treatment compared to their counterparts, supporting that DED associated with Sjögren’s syndrome requires/benefit from an anti-inflammatory and immunomodulatory therapy.

Conclusion:

Water-free ciclosporin 0.1% solution provides a clinically meaningful benefit to DED patients with Sjögren‘s syndrome.

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References: [1] Peng R, et al. JAMA Ophthalmol (2024) 142; 337-334

Disclosures: C. Cursiefen (none), Luo, Y. Shi (employees of Hengrui), V. L. Perez (consultant to Novaliq), A. Meides and S. Krösser (employees of Novaliq)

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