ONLINE-ONLY SUPPLEMENTARY MATERIAL

Supplementary Table I. Change in worst tear film osmolarity between both eyes after 6 months randomised treatment with CsA CE or vehicle in patients with baseline values >308 mOsms/L

	CsA CE n=154	Vehicle n=91	p value
Tear film osmolarity (mOsms/L)			
Baseline	n=34	n=21	
Mean±SD	331.0±20.2	321.5±10.5	
Median (min, max)	327.5 (309.0, 385.0)	319.0 (310.0, 346.0)	
Change at Month 6	n=25	n=17	
Mean±SD	–25.2±18.5	–9.5±17.5	
Adjusted mean (95% CI)[a]	–26.7 (–35.0, –18.3)	–16.7(–25.0, –8.4)	p=0.048
Median (min, max)	–24.0 (–72.0, 0.0)	–9.0 (–38.0, 19.0)	

Data represent a subgroup of the FAS population.

CsA CE: 0.1% ciclosporin A cationic emulsion; SD: standard deviation; 95% CI: 95% confidence interval.

[a] Means were adjusted for baseline values using an analysis of covariance (ANCOVA) model with the fixed factors: “treatment” and “pooled country” and the baseline data as covariate.

Supplementary Table II. Summary of adverse events recorded during the study

TEAEs	CsA CE 6 months n=154		Vehicle 6 months n=90		CsA CE 12 months n=154	
	n (%) patients	n events	n (%) patients	n events	n (%) patients	n events
Any TEAE	88 (57.1)	175	42 (46.7)	88	113 (73.4)	275
Any treatment-related TEAE	57 (37.0)	95	19 (21.1)	30	70 (45.5)	128
Any ocular TEAE	66 (42.9)	112	27 (30.0)	44	86 (55.8)	160
Any treatment-related ocular TEAEs	57 (37.0)	90	18 (20.0)	29	70 (45.5)	118
Any TEAE leading to discontinuation[a]	21 (13.6)	34	9 (10.0)	11	31 (20.1)	51
Any ocular TEAE leading to discontinuation	18 (11.7)	29	6 (6.7)	8	27 (17.5)	40
Any severe ocular TEAE	9 (5.8)	16	5 (5.6)	8	11 (7.1)	19
Any SAE[b]	6 (3.9)[b]	6[b]	6 (6.7)	6	14 (9.1)	14
Any treatment-related SAEs	0 (0.0)	0	1 (1.1)	1	0 (0.0)	0
Any ocular SAE	0 (0.0)	0	1 (1.1)	1	0 (0.0)	0
Deaths	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0

Data represent patients who received any amount of treatment over the specified time period.

CsA CE: 0.1% ciclosporin A cationic emulsion; TEAE: treatment-emergent adverse event; SAE: serious adverse event.

If a patient had multiple occurrences of an event, the patient was counted only once in the corresponding patient count.

[a] This category is about TEAEs that led to permanent discontinuation of treatment. All patients who stopped treatment were also discontinued from the study, except one patient who continued the study and completed the 6-month randomised treatment phase.

[b] There was 1 SAE that started during the double-masked period (up to Month 6) but its seriousness (i.e. event requiring hospitalization) was known by the investigators after the double-masked period database lock.