SAFETY AND EFFICACY OF 0.1% CICLOSPORIN CATIONIC EMULSION (CSA CE) IN SEVERE DRY EYE DISEASE (DED) PATIENTS DURING A 6-MONTH OPEN-LABEL PERIOD OF THE SANSIKA TRIAL

D. Ismail[1], M. Sainz de la Maza[2], F. Figueiredo[3], G. Geerling[4], M. Amrane[1], J. S. Garrigue[1], G. Garhöfer[5], B. Cochener[6]
[1]*Santen SAS, 1 rue Fontaine, France*
[2]*Ophthalmology Department, Hospital Clinic of Barcelona, Spain*
[3]*Royal Victoria Infirmary, Newcastle University, UK*
[4]*Department of Ophthalmology, University of Duesseldorf, Germany*
[5]*Clinical Pharmacology Department, Medical University Vienna, Austria*
[6]*Brest University Medical School, Morvan Hospital, France*

Purpose: Once-daily CsA CE improved ocular surface damage and inflammation in the SANSIKA trial. Here we describe the safety and efficacy of CsA CE during the open-label extension (OLE). Methods: A multi-center, double-masked, randomized, vehicle-controlled, Phase III trial of once-daily CsA CE in DED patients with severe keratitis (corneal fluorescein staining [CFS]=Grade 4 on modified Oxford scale). After completing the 6-month double-masked portion, patients entering the OLE received CsA CE and were monitored for safety and signs and symptoms of DED. Results: Overall, 207 patients initiated and 177 patients completed the OLE (114 continued CsA CE [C/C], 63 switched from vehicle [V/C]). During the OLE, treatment effects were maintained or further improved for the C/C group and improved in the V/C group. At Month 12, the CFS-ocular surface disease index (CFS-OSDI) responder rate (≥2-point CFS and ≥30% OSDI change) was similar in both groups (39.1% and 38.0%). CFS responder rate (≥2-point change) was higher in C/C patients (65.6%) versus V/C patients (54.4%). C/C patients were ~2 times more likely to achieve CFS score=0 at Month 12 (12.5%) vs Month 6 (6.5%). Human leukocyte antigen-DR expression improved similarly in both groups. As expected with CsA, the main adverse event (AE) was instillation-site pain. Treatment compliance (95%) and discontinuations due to ocular AEs were similar in both groups. Conclusion: Results from the SANSIKA OLE indicate that extending CsA CE treatment (up to 12 months) is safe and continues to improve signs and symptoms of DED in patients with severe keratitis.