

Effect of OC-01 (varenicline solution) Nasal Spray Compared to Vehicle Control on Dry Eye Disease Sign Outcomes by Baseline Subgroup Characteristics

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Author:

Dr. Leslie O'Dell, OD, FAAO
Medical Optometry America

Co-Author(s):

Andrea Gibson
Oyster Point Pharma
Dr Gretchen Blemker, OD
Oyster Point Pharma
Laura Hendrix
Oyster Point Pharma

Reviewer:

John Tassinari
Western

Submitter:

Dr Gretchen Blemker, OD
Oyster Point Pharma

Background:

Dry eye disease (DED) patients present with a broad range of clinical signs and symptoms at baseline (BL), including abnormal spectrum of Schirmer's Test Score (STS) and Eye Dryness Score (EDS) severity. OC-01 (varenicline solution) nasal spray (VNS) is a cholinergic agonist believed to pharmacologically neuro-activate the trigeminal parasympathetic pathway and increase basal tear production. To determine the effect of baseline signs and symptoms on the efficacy of OC-01 VNS, integrated data from ONSET-1 and ONSET-2 clinical trials were analyzed to determine their relevance on sign outcomes in DED subjects.

Methods:

Integrated data from ONSET-1 and ONSET-2 trials were analyzed to determine the mean change in STS (mΔSTS) (mm) from BL to Week 4 (W4) in OC-01 VNS 0.3mg and 0.06mg compared to vehicle control (VC) in DED subjects by subgroups pre-specified at BL: STS ≤5mm/>5mm, EDS <60/≥60. ANCOVA models include treatment, study number, study site, BL STS, and BL EDS as covariates.

Results:

Using last available data for missing assessments, OC-01 VNS 0.03mg and 0.06mg showed statistically significant ($p<0.01$) increases in mΔSTS from BL to W4 compared to VC for all subgroups: BL STS ≤5: 11.6mm, 12.1mm, 6.1mm; BL STS >5: 11.7mm, 11.6mm, 6.4mm; BL EDS <60: 12.3mm, 13.5mm, 6.2mm; BL EDS ≥60: 11.2mm, 10.5mm, 6.2mm, respectively. OC-01 VNS was associated with sneezing in both 0.03mg (82%) and 0.06mg (84%) groups, rated by the majority (98%) as mild. 22.4% of VC group subjects reported a sneeze. Treatment-Emergent Adverse Events (TEAEs) in >5% of subjects were cough, throat, and instillation site (nose) irritation.

Conclusion:

In the integrated ONSET-1 and ONSET-2 clinical trials data, treatment with OC-01 VNS, 0.03mg and 0.06mg, showed statistically significant increases in mΔSTS from BL to W4 in DED subjects compared to VC regardless of pre-specified BL subgroup. The most common TEAEs reported with OC-01 VNS were sneezing, cough, throat, and instillation site (nose) irritation within conditions of the studies. No drug-related Serious Adverse Events were reported. With its mechanism of action and route of administration, OC-01 VNS may potentially be an effective therapeutic option for increasing natural tear production in heterogenous DED patient populations.

Submitted By

Name:

Dr Gretchen Blemker, OD

Institution:

Oyster Point Pharma

Position/Title:

Medical Director

Address1:

202 Carnegie Center, Suite 109

City:

Princeton

State/Province:

NJ

Postal Code:

08540