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NOVATEARS® SIGNIFICANTLY STABILIZES THE TEAR FILM AND RELIEVES DRY EYE SYMPTOMS IN PATIENTS WITH EVAPORATIVE DRY EYE DISEASE

Study Findings Are Published in the Journal of Ocular Pharmacology and Therapeutics

Heidelberg, Germany – December 16, 2015 – NovaTears®, the first commercially available topical eye drop from Novaliq GmbH for the treatment of evaporative dry eye disease (DED), was found to significantly improve four of five measures associated with evaporative DED, new research shows. NovaTears was also shown to be safe and well tolerated, and caused no changes in visual acuity or intraocular pressure (IOP). The decrease of the Ocular Surface Disease Index (OSDI) by a mean of 21 points exceeded minimal, clinical important differences for mild or moderate and severe disease.

These findings were published recently in the *Journal of Ocular Pharmacology and Therapeutics*.

About the Study

Thirty patients with evaporative DED received NovaTears (perfluorohexyloctane F6H8) during a prospective, multicenter, observational, 6-week study. Subjects applied one drop of NovaTears to both eyes four times daily and returned six weeks later for follow up. Parameters assessed included best-corrected visual acuity (BCVA), IOP, Schirmer I test, tear fluid, tear film breakup time (TFBUT), corneal staining, meibum secretion, and OSDI. Twenty-five subjects completed the study per protocol, of which 24 were female, and one was male.

After six weeks of use, NovaTears treatment led to a significant reduction of corneal staining, and a significant increase of Schirmer I and TFBUT. In addition, OSDI score dropped significantly from a mean of 55 (± 23.0) to 34 (± 22.4). Visual acuity and IOP did not change.

“These findings strongly suggest that NovaTears significantly and safely relieves many of the symptoms associated with evaporative DED,” says study co-author Philipp Steven, MD, Principal Investigator, Department of Ophthalmology, Ocular GvHD Competence Center, University of Cologne, Germany. “The decrease of the OSDI by a mean of 21 points is particularly remarkable and clearly exceeds minimal, clinical important differences for mild, moderate and even severe disease. What’s more, NovaTears’ novel non-blurring, water-free formulation demonstrates strong spreading abilities due to an extremely low surface tension of just 19.65 mNm compared to water at 72 mNm.”

The significant decrease in corneal staining can be seen in the shift of the number of patients diagnosed with Grade 1 or Grade 2 at baseline toward Grade 0 at follow up. At baseline, 11 eyes were Grade 0, 29 were Grade 1, and eight were Grade 2. At the end of the study, 37 eyes were Grade 0, 10 were Grade 1, and one eye was Grade 2.

Tear secretion and tear film stability improved significantly over the study period as can be seen in the increase in Schirmer I and the TFBUT. Schirmer I test showed increases from 10.5 ± 4.1 mm/5min in the right eye to 16.6 ± 9.8 mm/5min (OD: $P=0.0040$), and in the left eye from 10.2 ± 4.2 mm/5min to 15.9 ± 9.7 mm/5min (OS: $P=0.0013$). TFBUT increased from 6.0 ± 2.5 s in the right eye to 8.8 ± 4.9 s (OD: $P=0.0026$), and in the left eye from 5.8 ± 2.6 s to 9.6 ± 5.9 s (OS: $P=0.0006$).

Patient meibum was examined at both baseline and follow up visit, and improved in some cases. In seven cases, no expressible meibum was reported at study conclusion. Overall safety and tolerability was good, 5 adverse events were reported in the whole study, which were all of mild to moderate intensity.

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"This new study supports the safety and efficacy of NovaTears, and provides clinical endorsement for patients with evaporative dry eye disease," says Bernhard Günther, Managing Director and CEO of Novaliq GmbH.

"Novaliq's study clearly demonstrates that NovaTears offers significant benefits to patients with evaporative dry eye disease, and further validates Novaliq as an emerging company providing innovative ocular disease therapeutics," says Jerry Cagle, PhD, board member, Novaliq GmbH.

This study was supported by Novaliq GmbH, Heidelberg, Germany.

Source: Steven P, et al. Semifluorinated Alkane Eye Drops for Treatment of Dry Eye Disease—A Prospective, Multicenter Noninterventional Study. Journal of Ocular Pharmacology and Therapeutics (2015), https://www.researchgate.net/publication/281167218_Semifluorinated_Alkane_Eye_Drops_for_Treatment_of_Dry_Eye_DiseaseA_Prospective_Multicenter_Noninterventional_Study.

About Novaliq – Novaliq GmbH, founded in 2007, is a Heidelberg based specialty pharmaceutical and drug delivery company with the mission to transform poorly soluble drugs into effective ocular therapeutics for both front and back of the eye. Novaliq's proprietary technology enhances the topical bio availability, stability and safety of traditionally insoluble or unstable drugs improving the delivery, efficacy and convenience of treatments for ocular surface diseases including dry eye through preservative free and multi dose formulations. Novaliq's most advanced product is NovaTears® with CE-marking based on Novaliq's proprietary EyeSol® Technology. NovaTears is marketed under the brand name EvoTears™ in Europe. **More on www.novaliq.com.**

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