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NOVALIQ ANNOUNCES PUBLICATION OF SECOND PIVOTAL PHASE 3 TRIAL DATA ON CYCLASOL 0.1% (CYCLOSPORINE OPHTHALMIC SOLUTION) IN JAMA OPHTHALMOLOGY

Heidelberg, Germany, and Cambridge, MA, USA, April 12, 2023 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that results from the second pivotal Phase 3 trial for CyclASol®, ESSENCE-2, have been published in Journal of the American Medical Association (JAMA) Ophthalmology. CyclASol® is currently under regulatory review for the treatment of signs and symptoms of dry eye disease (DED). The U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) action date of June 8, 2023.

The publication titled "**Efficacy and Safety of a Water-Free Topical Cyclosporine 0.1% Solution for the Treatment of Moderate to Severe Dry-Eye Disease: ESSENCE-2, a Randomized Clinical Trial**" reported that CyclASol® shows early therapeutic effects on the ocular surface. This study evaluated corneal staining responders to get a better understanding of how many patients benefit from the treatment. A ≥ 3 score improvement of corneal staining on the National Eye Institute (NEI) scale is an immediately noticeable and clinically meaningful response of a dry eye disease therapy[1]. In ESSENCE-2, 71.6% of CyclASol® treated patients showed such a response after 4 weeks of treatment, significantly more than in the vehicle group. Notably, the study showed that a ≥ 3 score of corneal staining improvement was associated with significant improvements in a variety of patient reported symptoms, establishing a correlation between the magnitude of improvement in the physician-measured clinical signs and the patient-reported symptoms.

According to Dr. Esen Akpek, MD, professor of ophthalmology at the Wilmer Eye Institute of Johns Hopkins hospital, Baltimore, MA and primary author of the publication, corneal staining represents the single most critical clinical parameter for DED due to its direct and indirect impact on vision. As reported, the rapidity of the onset as well as the magnitude of effect of CyclASol® 0.1%, twice-daily eye drop solution, on corneal staining has not been shown with any of the currently used therapies. The profile combined with demonstrated tolerability may provide distinct clinical benefit to patients and eye care professionals alike when the product is approved.

CyclASol® consists of the water-insoluble active pharmaceutical ingredient cyclosporine solubilized in a novel, water-free excipient, perfluorobutylpentane. This makes CyclASol® the first water-free drug solution without requirement to use any preservatives, oils, or surfactants, which can be irritating and disturbing for the tear film.

"High quality clinical research and scientific communications of the results are key strengths at Novaliq," said Dr. Christian Roesky, CEO Novaliq. "The breadth and depth of the scientific publications on CyclASol® in peer-reviewed journals provides increasing evidence on the clinical value of our water-free technology to address unmet patient and medical needs".

About Novaliq

Novaliq is a private biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology. EyeSol® is Novaliq's proprietary water-free technology using ultrapure semifluorinated alkanes (SFAs) that are physically, chemically, and physiologically inert with excellent biocompatibility and a very good safety profile. Two EyeSol® dry eye drug products are in regulatory reviews by U.S. FDA: CyclASol® and NOV03 (perfluorohexyloctane) with PDUFA target action dates on June 8 and 28, 2023 respectively. In the EU perfluorohexyloctane is registered as a medical device to treat patients with dry eye disease since 2013. The company continues to progress into other ophthalmic indications based on its validated EyeSol® platform.

Novaliq GmbH is headquartered in Heidelberg, Germany and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on www.novaliq.com.

Recommended Readings

1. Holland EJ, Jackson MA, Donnenfeld E, et al. Efficacy of Lifitegrast Ophthalmic Solution, 5.0%, in Patients With Moderate to Severe Dry Eye Disease: A Post Hoc Analysis of 2 Randomized Clinical Trials. JAMA Ophthalmol. 2021 Nov 1;139(11):1200-1208