Novaliq Media Contact:
Simone Angstmann-Mehr
info@novaliq.com

NOVALIQ ANNOUNCES FDA ACCEPTANCE OF THE NEW DRUG APPLICATION FOR CYCLASOL® FOR THE TREATMENT OF DRY EYE DISEASE

- PDUFA target action date is June 8, 2023

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, October 24, 2022 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for CyclASol® (cyclosporine ophthalmic solution), a first-of-its-kind anti-inflammatory product for the treatment for the signs and symptoms of dry eye disease (DED).

The Agency completed the filing review of the CyclASol® NDA and determined that the application is sufficiently complete to permit a substantive review. No potential review issues have been identified at this time. The Prescription Drug User Fee Act (PDUFA) target action date set by the FDA for announcing its decision on Novaliq's NDA after reviewing the application is June 8, 2023.

"This is an exciting time for ophthalmologists and optometrists and their patients as we are one step closer to address important needs and to better treat a serious ocular surface condition affecting millions of Americans", said Christian Roesky, Ph.D., CEO, Novaliq. "If approved, CyclASol® would be a highly potent but comfortable anti-inflammatory therapy for patients with dry eye disease. It shows impressive and rapid therapeutic effects objectively measured on the ocular surface in the majority of patients, with clinical benefits on the signs and symptoms of the disease."

CyclASol® has demonstrated in two pivotal studies fast onset of therapeutic effect in afflicted patients in this indication, clinical meaningful improvement of ocular surface damage, and excellent tolerability. Results from a 12-month long-term study confirmed that the effects are maintained, and even improved for most sign and symptom endpoints.

"This important milestone marks the second NDA acceptance of water-free dry eye therapies in less than 3 months.[1] The two distinct modalities of action of the EyeSol®-based dry eye therapies open new and complimentary clinical prospects on how to treat DED in the future," said Sonja Krösser, Ph.D., Vice President Preclinical & Clinical Development at Novaliq. "We are committed to work closely with the FDA to bring this novel cyclosporine drug product to patients suffering from DED as quickly as possible."

Dry eye is one of the most common ocular surface disorders, with approximately 18 million Americans diagnosed with DED.[2,3] Inflammation and immunologic processes play a key role in the pathology of the disease.

Novaliq further plans to submit a marketing authorization application to the European Medicines Agency and further authorities in 2023.

About Novaliq
Novaliq is a 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. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases.

In September 2022 acceptance of filing of a New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) was announced for NOV03 (perfluorohexyloctane), for the proposed indication of treating the signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD). PDUFA target action date for NOV03 is June 28, 2023. In addition to CyclASol®, the company continues to progress multiple additional pipeline opportunities based on its validated EyeSol® platform, both in ophthalmology and adjacent indications like dermatology.

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. https://www.novaliq.com/press-releases/2022/09/07/fda-accepts-nda-filing-for-nov03/
2. Leonardi A, Modugno RL, & Salami E. Allergy and Dry Eye Disease. Ocular immunology and inflammation. 2021; 29:1168–1176
3. 2020 Dry Eye Products Market Report: A global Analysis for 2019 to 2025. Market Scope

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