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NOVALIQ PLANS TO FILE A MARKETING AUTHORISATION APPLICATION FOR CYCLASOL® IN THE E.U. FOR THE TREATMENT OF DRY EYE DISEASE IN JULY 2023

- CHMP determined CyclASol is eligible for a centralised procedure
- Novaliq has submitted a Letter of intent to file a Marketing Authorisation Application (MAA) in July 2023

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, Feb 8, 2023 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced its plans for filing a Marketing Authorisation Application (MAA) for CyclASol® (ciclosporin ophthalmic solution), a first-of-its-kind anti-inflammatory product for the treatment of dry eye disease (DED) in the European Union.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) determined that CyclASol® is eligible to be reviewed in a centralized procedure to receive a Union Marketing Authorisation for the European Economic Area (EEA). In December 2022, EMA stated in its response that, based on the documentation provided by Novaliq, a submission is in the interest of patients at Community level under Article 3(2)b - Interest of patients of Regulation (EC) No 726/2004. Consequently, Novaliq has submitted a letter of intent to EMA to file the MAA in July 2023.

Dry eye is one of the most common ocular surface disorders with approximately 15 million diagnosed patients in the 5 largest European countries[1]. Treatment options for DED in the European market are limited, with only one approved drug therapy restricted to the treatment of severe keratitis associated with DED[1].

CyclASol® consists of cyclosporine solubilized in a novel water-free excipient, perfluorobutylpentane, and is the first available solution developed with the water-insoluble cyclosporine. This water-free drug product does not require preservatives, oils or surfactants, which can be irritating and disturb the tear film. The superior tolerability of CyclASol® has been proven clinically.

“I see many patients in my practice whose lives are impacted by dry eye disease. New approved drug therapies for these patients in Europe are very welcome.” said Christophe Baudouin, MD, PhD, FARVO, Professor of Ophthalmology at Quinze-Vingts National Ophthalmology Hospital and President of the European Dry Eye Society “Having a comfortable product that provides clinically meaningful improvements of the ocular surface as early as 2 weeks is addressing an important medical need and could help to limit steroid use."

CyclASol® has demonstrated in two independent adequate and well-controlled, multicenter studies (ESSENCE-1[2] and ESSENCE-2) clinically meaningful and statistically significant improvements in moderate to severe patients affected by the disease indication. Effects on the ocular surface include a statistically significant reduction in total corneal fluorescein staining score favoring CyclASol® as early as on Day 15. Up to 71.6% of patients responded within four weeks with a clinically meaningful improvement in total corneal staining. This proportion of responders was significantly higher compared to vehicle-treated

patients in both studies. Patients responding also showed statistically significant improvements in a variety of symptoms compared to non-responders within 4 weeks. CyclASol® has a favorable tolerability profile demonstrating high patient acceptance and an improved side effect profile. Continued improvement under therapy in both, signs and symptoms of DED, has been clinically demonstrated over a period of up to 56 weeks also confirming the favorable tolerability profile.

"CyclASol® was specifically developed as a potent and comfortable anti-inflammatory dry eye drug therapy with rapid onset of effect for dry eye patients not adequately responding to artificial tears", said Christian Roesky, Ph.D., CEO, Novaliq. "We are excited by the response of the European Medicines Agency and look forward to hopefully bring CyclASol® to patients in Europe, and ultimately address an unmet medical need for those suffering with dry eye disease."

In the United States the Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) target action date for the CyclASol® New Drug Application (NDA) on June 8, 2023.

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 review 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. Global Data. Dry Eye Syndrome: Seven-Market Drug Forecast and Market Analysis Update | December 2022
2. Sheppard et al. A Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase 2B/3 ESSENCE Study. Cornea. 2021 Oct 1;40(10):1290-1297