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NOVALIQ RECEIVES POSITIVE CHMP OPINION FOR VEVIZYE® IN DRY EYE DISEASE

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, July 29, 2024 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, announces that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a marketing authorisation in the European Union for Vevizye®, intended for the treatment of moderate to severe dry eye disease in adult patients, which has not improved despite treatment with tear substitutes.

Dry eye disease (DED) is one of the most common ocular surface disorders, affecting approximately 15 million diagnosed patients in the five largest European countries[1] and is difficult to treat[2]. In Europe treatment options for DED are limited, with only one approved drug therapy restricted to the treatment of severe keratitis associated with DED[1].

Vevizye®, development name CyclASol®, is a clear ciclosporin 0.1% solution, free of oils, surfactants, and preservatives, offering superior spreading properties and increased residual time on the ocular surface. This unique water-free therapy unfolds the full potential of ciclosporin to efficiently treat dry eye disease – fast and comfortable for patients.

Novaliq submitted a Marketing Authorisation Application (MAA) for Vevizye® in July 2023 under the centralised procedure. The positive opinion is based on the CHMP review of the comprehensive data package from more than 1.500 patients with moderate to severe DED.

"Clinical data for Vevizye® showed clinically meaningful improvements of the ocular surface as early as two weeks, combined with an excellent tolerability profile and high treatment satisfaction," said Professor José M. Benítez del Castillo, Chair of the Department of Ophthalmology at University Complutense Madrid (Spain). "I am enthusiastic that there will be a new treatment option addressing these important aspects of a dry eye therapy in Europe."

Vevizye® demonstrated clinically meaningful and statistically significant improvements in moderate and severe DED patients in two independent adequate and well-controlled, multicenter studies (ESSENCE-1[3] and ESSENCE-2[4]) across various endpoints. These included effects on the ocular surface with a statistically significant reduction in total corneal fluorescein staining score favoring Vevizye® as early as on Day 15. Up to 71.6% of patients responded within four weeks with a clinically meaningful improvement in total corneal fluorescein staining. Responders showed statistically significant improvements in a variety of symptoms compared to non-responding patients within four weeks. Continued and relevant improvement under therapy in both signs and symptoms of DED were demonstrated over a period of up to 56 weeks, confirming Vevizye®'s favorable tolerability and efficacy profile.

"The positive CHMP opinion for Vevizye® marks a major achievement and the pinnacle of our extensive research in dry eye disease therapies. If the marketing authorisation in the EU is formally granted, this unique water-free ciclosporin therapy will be the first medicinal therapy approved to treat dry eye disease in the US and EU," said Sonja Krösser, PhD, Vice President Medical Science and Regulatory Affairs. "DED is a serious and difficult to treat condition. Clinically meaningful outcomes in the majority

of patients are key differentiators for eyecare providers, patients and payers. Vevizye® demonstrated across multiple studies that most patients benefit from the therapy already after two weeks showing continued improvements over 12 months in both signs and symptoms."

In May 2023 the United States Food and Drug Administration (FDA) approved CyclASol® under the brand name Vevye™. The product was successfully launched in the United States in January 2024 by Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company.

About Novaliq

Novaliq is a private biopharmaceutical company focusing on the development of first- and best-in-class ocular therapeutics. Novaliq developed EyeSol®, a novel drug category of water-free topical eye medicines. Two FDA-approved EyeSol® medicinal products for dry eye disease - Miebo™ and Vevye™ - have recently been launched in clinical practices of eyecare professionals in the US and are beginning to revolutionize patient care. The EyeSol®-based products for dry eye disease are successfully partnered in major markets and are under regulatory review in several further countries and regions.

The Novaliq R&D pipeline provides multiple opportunities for development in ophthalmology and retina therapies.

Novaliq is headquartered in Heidelberg, Germany and 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. Jones et al. TFOS DEWSII Management and Therapy Report. The Ocular Surface. 2017; 15 (3): 575-628
3. 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
4. Akpek et al. Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease The ESSENCE-2 Randomized Clinical Trial. JAMA Ophthalmology. 2023; 141(5):459-466

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