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European Medicines Agency Accepts Novaliq's Marketing Authorization Application for CyclASol® (ciclosporin ophthalmic solution) 0.1% for the Treatment of Dry Eye Disease

Heidelberg, Germany, and Cambridge, MA, USA, August 24, 2023 – Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced that the European Medicines Agency (EMA) has accepted the marketing authorization application (MAA) for CyclASol (ciclosporin ophthalmic solution) for regulatory review. CyclASol is an investigational new drug treatment for dry eye disease in patients not responding to tear substitutes. The Committee for Medicinal Products for Human Use (CHMP) of the EMA will start its review of the MAA under the centralized procedure for all 27 member states of the European Union (EU).

Dry eye disease (DED) affects millions of people in Europe and is one of the most common ocular surface disorders. A leading cause of DED is inflammation of the ocular surface. The chronic inflammatory nature causes progressive corneal surface damage that can lead to direct or indirect visual impairment. In the EU only one drug therapy limited to a subset of DED patients with severe keratitis is currently approved.

CyclASol is ciclosporin, solubilized in a novel, water-free excipient and was designed to address unmet needs, providing patients with a fast acting and well tolerable dry eye drug therapy. Dispensed in a unique 10 microliter small drop the solution does not contain water or anti-microbial preservatives, oils or surfactants. As a water-free product, there is no associated pH and no osmolarity.

"Our in Heidelberg, Germany, invented water-free technology was designed to unfold the full potential of pharmaceuticals on the ocular surface," said Christian Roesky, Ph.D., Chief Executive Officer of Novaliq. "The acceptance of the EU Marketing Authorization Application is a key milestone in our global efforts to address high unmet needs to better serve patients suffering from dry eye disease. We look forward to collaborating with the CHMP throughout the review process and hope to make CyclASol available for patients in Europe."

The clinical development program for the MAA is based on six clinical studies, which evaluated the safety and efficacy of CyclASol in a total of 1,575 patients with dry eye disease. Results from the two registrational studies, ESSENCE-1 and ESSENCE-2 consistently demonstrated that the product is effective for the treatment of DED. Continued improvement under therapy in both signs and symptoms of DED has been clinically demonstrated over a period of up to 56 weeks in an extension study of ESSENCE-2. With its early onset of effect and its good tolerability profile CyclASol addresses unmet medical needs in DED.

CyclASol was approved by the U.S. Food and Drug Administration (FDA) as VEVYE™ (cyclosporine ophthalmic solution) 0.1% for the treatment of the signs and symptoms of dry eye disease on May 30, 2023. VEVYE is the first and only FDA approved cyclosporine solution indicated for the treatment of signs and symptoms of dry eye disease with efficacy demonstrated after 4 weeks of treatment and is commercialized in Northern America by Harrow Health Inc, a leading U.S. eyecare pharmaceutical company.

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 ophthalmic technology.

Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases based on its proprietary water-free eyedrop technology. On May 18th, 2023, U.S. Food and Drug Administration (FDA) approved MIEBO™ (perfluorohexyloctane ophthalmic solution; formerly known as NOV03) followed by the approval of VEVYE™ (cyclosporine ophthalmic solution, development name CyclASol®) 0.1% on May 30th, 2023.

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 novaliq.com.

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