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NOVALIQ COMPLETES ENROLLMENT OF SECOND PHASE 3 STUDY FOR CYCLASOL® FOR THE TREATMENT OF DRY EYE DISEASE

HEIDELBERG, Germany, and CAMBRIDGE, MA, August 10, 2021 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced the second of two Phase 3 (ESSENCE-2) studies, evaluating the investigational drug CyclASol® to treat the signs and symptoms of dry eye disease DED, has been completely enrolled with a total of 834 participants.

Dry eye disease, one of the most common ocular surface disorders, impacts quality of life for millions of people. Although a multifactorial chronic disease, inflammation and immunologic processes play a key role in the pathology of dry eye. Infiltration of immune cells in the lacrimal glands, meibomian glands, conjunctiva, and cornea are dominating characteristics in dry eye disease. The inflammatory vicious cycle includes tear film instability, tear hyperosmolarity, apoptosis of corneal/conjunctival cells, inflammation in the ocular surface and ocular damage. Intrinsic and extrinsic factors cause stress to the ocular surface, which accelerates the cycle and, in turn, exacerbates dry eye.[1]

The Phase 3 program for CyclASol® also includes a completed multi-center, randomized, double-masked, vehicle-controlled trial in 328 patients (ESSENCE-1), and an ongoing multi-center, open-label, single-arm 12-month safety extension trial in 202 patients (ESSENCE-2 OLE). Results from ESSENCE-2 are expected in Q4 2021 and, if positive, will allow for a New Drug Application (NDA) filing to the U.S Food and Drug Administration in 2022.

“We are very pleased with the progress of the Phase 3 program for CyclASol® and thank the patients, study sites and investigators who participate in this program. We are hopeful the results of the ESSENCE-2 study will be consistent with the results of the ESSENCE-1 trial and confirm efficacy and safety results from the earlier phases of the development program ,” said Sonja Krösser, Ph.D., Vice President Pre-Clinical and Clinical Development, Novaliq.

CyclASol® is a topical, anti-inflammatory and immunomodulating ophthalmic solution, containing 0.1% cyclosporine A in EyeSol®, developed for the treatment of DED. The unique water-free drug product is based on the EyeSol® enhanced ocular bioavailability technology that allows for several fold higher corneal penetration of cyclosporine A in comparison to water or oil-based formulations.[2] This has led to the differentiated therapeutic profile of CyclASol® with an early onset of efficacy within 2 weeks and significantly improved tolerability.

“If approved, CyclASol® may offer a first-in-time anti-inflammatory treatment for the signs and symptoms of dry eye disease with an early onset of action, high efficacy and good tolerability,” said Christian Roesky, CEO, Novaliq. “We anticipate to submit a New Drug Application for CyclASol® to the U.S. Food and Drug Administration in 2022.”

About CyclASol® Ophthalmic Solution

CyclASol® is a topical anti-inflammatory and immunomodulating ophthalmic solution, containing 0.1% cyclosporine A in EyeSol®, developed for the treatment of dry eye disease. The unique water-free formulation increases residual time on the ocular surface and enables a high bio-availability in the target tissues to unfold the full potential of cyclosporine A. The multi-dose, preservative-free, smaller and more physiologic droplet size profile provides unique clinical benefits and outstanding tolerability. Notably, the improvement in visual function associated with a clinically significant reduction of corneal staining, as shown in the recent Phase 2/3 clinical ESSENCE-1 trial, will differentiate CyclASol® from existing therapies and are published in [Cornea: The Journal of Cornea and External Disease](#). [3] In addition to the Phase 3 program, the results from a dose-finding, vehicle-controlled Phase 2 clinical study with an open-label comparator arm (Restasis™, Abbvie) evaluating CyclASol® were published in [Ophthalmology](#). [4]

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

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