

NOVALIQ

Transforming Ocular Therapeutics

Novaliq Announces First Patient Randomized in the Phase 3 trial ESSENCE-2 of CyclASol® Topical Ophthalmic Solution for the Treatment of Dry Eye Disease

- ESSENCE-2 is the second registration trial to complete the clinical development of CyclASol® as agreed with U.S. Food and Drug Administration (FDA)
- Designed to replicate efficacy demonstrated in previous phase 2/3 ESSENCE-1 trial
- Topline data expected in 2nd half 2021

Heidelberg – December 8, 2020 - Novaliq, a pharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that it has initiated the randomization of patients in its phase 3 clinical trial ESSENCE-2 that is designed to replicate efficacy results of the previous phase 2/3 ESSENCE-1 trial.

“The initiation of this second registrational trial represents a key milestone for both CyclASol® and our company,” says Sonja Krösser, PhD, Vice President Clinical Development at Novaliq. “Our program has been agreed upon by the U.S. Food and Drug Administration. If ESSENCE-2 is successful, we will have sufficient clinical evidence to support a New Drug Application for CyclASol® for the treatment of the signs and symptoms of dry eye disease in 2022.”

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 has led to a differentiated therapeutic profile with an early onset of efficacy and improved tolerability for patients with dry eye disease. The previous phase 2/3 clinical trial ESSENCE-1 demonstrated statistically significant improvements with CyclASol® in both sign and symptom endpoints as compared to its vehicle after 4 weeks. Additionally, the trial demonstrated that reading speed improves with corneal staining reduction. Safety and tolerability in the trial were excellent. [1]

“The pronounced effects on corneal staining resulting in improvement in visual function and the excellent tolerability profile seen with CyclASol® addresses an important medical need for patients with chronic dry eye disease,” said Laura Periman, MD, Founder and Director of Dry Eye Services and Clinical Research at Periman Eye Institute. “We are excited to participate in ESSENCE-2, thereby bringing this promising product candidate one step further to patients suffering from predominately aqueous deficient dry eye disease.”

The ESSENCE-2 trial is a multicenter, randomized, double-masked, vehicle-controlled clinical trial to assess efficacy, safety and tolerability of CyclASol® for the treatment of signs and symptoms of dry eye disease. The trial is planned to enroll approximately 834 subjects in about 25 U.S. clinical centers and is being conducted by Ora, Inc., the world’s leading full-service ophthalmic clinical research organization (CRO). The pre-specified primary endpoints of the trial are the change from baseline in total corneal staining and in eye dryness score at day 29. The trial will include the assessment of reading speed as an objective and quantifiable measurement of visual function. About 200 patients will be rolled over in an open-label extension trial to assess the long-term safety over a period of one year. The company expects to publish topline data from ESSENCE-2 in the 2nd half of 2021.

COVID-19 Situation

Due to potential delays caused by COVID-19, the Company is not providing a target date for the ESSENCE-2 topline results. Although Novaliq and Ora currently do not anticipate delays to the clinical timelines, we will closely monitor the situation during the trial and provide regular information on development timelines.

About Novaliq

Novaliq is a pharmaceutical 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 need 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.

Media contact for Novaliq:

Simone Angstmann-Mehr, Novaliq GmbH, info@novaliq.com

Sources:

[1] Sheppard JD et al. A Waterfree 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase II/III ESSENCE Study. Cornea, in press