Novaliq Announces More than 50% Patients Enrolled in CyclASol® Phase 3 Dry Eye Disease Trial ESSENCE-2

- Topline results expected in 2nd half 2021; 475 out of a 834 target patients randomized in ESSENCE-2
- Enrollment for 12-month safety extension trial (ESSENCE-2 OLE) completed
- Phase 2B/3 Trial ESSENCE-1 Published in Cornea: The Journal of Cornea and External Disease

Heidelberg and Cambridge, MA – April 28, 2021 - Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that the second Phase 3 clinical trial evaluating CyclASol® to treat the signs and symptoms of dry eye disease (DED) has randomized more than 50% out of 834 targeted patients, with top-line results expected in the 2nd half of 2021.

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

"We have been very successful in maintaining a good recruitment rate in the ESSENCE-2 trial through careful selection and support of our clinical sites, despite the COVID-19 pandemic environment," said Sonja Krösser, Ph.D., Vice President Clinical Development at Novaliq. "Patients had the opportunity to roll-over into the open-label 12-month safety extension trial and we are pleased to report that the ESSENCE-2 OLE trial has been completely enrolled with a total of 200 participants. Achieving these two enrollment milestones indicates that we are on track with the CyclASol® development program to file our first NDA in 2022."

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 [1]. This has led to the differentiated therapeutic profile of CyclASol® with an early onset of efficacy within 2 weeks and significantly improved tolerability.

The previous Phase 2B/3 clinical trial ESSENCE-1 which evaluated the efficacy, safety, and tolerability of CyclASol® in patients with DED has been published in Cornea: The Journal of Cornea and External Disease [2]. In this study, CyclASol® demonstrated statistically significant improvements in pre-specified endpoints for both signs and symptoms of DED as compared to its vehicle after 4 weeks. Consistent with results from an earlier Phase 2 trial [3], CyclASol® showed clinically meaningful improvements in both corneal and conjunctival staining to monitor the ocular surface condition and improvements in symptoms of dryness compared with those of its vehicle. Additionally, the ESSENCE-1 trial demonstrated that reading speed improves with the corneal staining reduction. Safety and tolerability in the trial were excellent with outstanding application comfort scores which are usually only reported with lubricating eye drops [2].

The ongoing 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 DED. The trial is planned to enroll approximately 834 subjects in about 25 U.S. clinical centers. The 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 again include the assessment of reading speed as an objective and

quantifiable measurement of visual function. The company expects to publish topline data from ESSENCE-2 in the 2nd half of 2021.

“We sincerely thank all patients, investigators and their local site personnel for participating in this study, as well as the entire research and development team in the U.S. and Heidelberg for their dedication and hard work to achieve this important milestone, particularly under the additional complexities due to the COVID-19 pandemic,” said Christian Roesky, Ph.D., CEO, Novaliq.

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 eye-drop 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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Sources:

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[2] Sheppard JD et al. A Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase II/III ESSENCE Study. Cornea, January 2021, Publish Ahead of Print https://doi.org/10.1097/ICO.0000000000002633

[3] Wirta DL et al. A Clinical Phase II Study to Assess Efficacy, Safety, and Tolerability of Waterfree Cyclosporine Formulation for Treatment of Dry Eye Disease. Ophthalmology, Volume 126 (2019) 793-800