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NOVALIQ PRESENTS DATA FROM SECOND PHASE 3 TRIAL OF INVESTIGATIONAL TREATMENT CYCLASOL® (0.1% CYCLOSPORINE OPHTHALMIC SOLUTION) AT THE AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY ANNUAL MEETING

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, April 26, 2022 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that data from the second pivotal Phase 3 trial (ESSENCE-2) evaluating the investigational drug CyclASol® for the treatment of dry eye disease (DED), was presented as part of a podium symposium at the American Cataract and Refractive Surgery (ASCRS) annual meeting in Washington D.C. on April 24, 2022.

CyclASol® is the first topical preservative-free, water-free, anti-inflammatory and immunomodulating ophthalmic solution, containing 0.1% cyclosporine in a novel vehicle, developed for the treatment of the signs and symptoms of DED.

“The ESSENCE-2 data confirms that CyclASol® has consistent and superior therapeutic effects on the ocular surface in patients with dry eye disease. These became significant after 15 days, and 71.6% of patients showed a clinically meaningful improvement in total corneal fluorescein staining at 4 weeks. Patients with high central staining scores showed superior relief of blurred vision in the CyclASol® group compared to vehicle”, highlighted John D. Sheppard, MD, MMSc, FACS, Professor of Ophthalmology at Eastern Virginia Medical School, Mid-Atlantic Medical Director for Eye Care Partners, and leading CyclASol® trial investigator. “The fact that 78.6% of patients rated their satisfaction with CyclASol® as positive or neutral underlines the excellent safety and tolerability profile of this novel water-free drug therapy to treat inflammatory corneal surface damage secondary to dry eye disease.”

DED, one of the most common ocular surface disorders, negatively affects the quality of life for millions of people. Progressive corneal surface damage secondary to DED can lead to visual impairment and has a measurable impact on activities requiring sustained visual attention, including reading, driving, and work productivity.[1] Corneal surface damage can have deleterious effects on visual outcomes of ophthalmologic surgeries including cataract and LASIK surgery and multiple guidelines recommend treatment of corneal surface damage secondary to DED prior to elective ocular procedures or treatments.[2-5]

“There is a high unmet need for a rapid, consistent, safe, sustained, and comfortable treatment for dry eye disease. These data support that CyclASol® potentially has the power eye care professionals require with the comfort their dry eye disease patents desire,” said Dr Christian Roesky, Chief Executive Officer Novaliq. “We intend to submit for approval in the USA in July 2022.”

ESSENCE-2 is an 834 subject 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 in patients not responding to artificial tears. Key results include:

- On day 15 and 29, change from baseline in total Corneal Fluorescein Staining (tCFS) was statistically significant in the CyclASol® group compared to the vehicle group (p values = 0.0022 and 0.0278 respectively)
- On day 29, the proportion of patients showing a clinically meaningful improvement in tear production (≥10 mm increase) was statistically significantly higher compared to the vehicle (p = 0.0487)
- Additionally, 71.6% of CyclASol® treated patients had a ≥3 grade improvement in tCFS at week 4. The proportion of responders was significantly higher compared to vehicle-treated patients (p = 0.0002).
- These responders also showed statistically significant improvements in a variety of symptoms including but not limited to Dryness (p = 0.0074) compared to non-responders at day 29.

CyclASol® was well tolerated showing an excellent ocular safety profile. The number of all adverse events (AEs) and ocular AEs, including instillation site reactions, were low. 99.8% of patients experienced no or mild instillation site pain. AEs were generally of mild intensity and similarly distributed between the two treatment groups. Up to 86.5% of the patients reported an immediate feeling of comfort when describing CyclASol® water-free eye drops.

About Dry Eye Disease

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 dominant characteristics in dry eye disease. The inflammatory vicious cycle includes tear film instability, hyperosmolarity, inflammation and damage to the corneal and conjunctival epithelium. Intrinsic and extrinsic factors cause stress to the ocular surface, which accelerate the cycle and, in turn, exacerbate dry eye.[6]

About CyclASol® Ophthalmic Solution

CyclASol® is a topical anti-inflammatory and immunomodulating ophthalmic solution, containing 0.1% cyclosporine in EyeSol®, developed for the treatment of dry eye disease. The multi-dose, preservative-free, smaller and more physiologic droplet size profile provides unique clinical benefits and outstanding tolerability. Notably, an improvement in visual function associated with a clinically significant reduction of central corneal staining, as shown in clinical trials, differentiates CyclASol® from existing therapies and are published in Cornea: The Journal of Cornea and External Disease.[7] Results from a dose-finding, vehicle-controlled Phase 2 clinical trial with an open-label comparator arm (Restasis™, Abbvie) evaluating CyclASol® were published in Ophthalmology.[8] The clinical development program for CyclASol® is expected to conclude with an ongoing multi-center, open-label, single-arm, 12-month safety extension trial (ESSENCE-2 OLE).

About Novaliq

Novaliq is a biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on the worldwide first water-free technology EyeSol®. Novaliq's proprietary water-free EyeSol® technology uses ultrapure semifluorinated alkanes (SFAs) that

are physically, chemically, and physiologically inert with excellent biocompatibility and a very good safety profile. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. CyclASol® is the first drug product evaluated in a phase 3 clinical program utilizing EyeSol® as a vehicle to enhance topical bioavailability of the drug on the ocular surface and at the same time provide outstanding comfort and tolerability. 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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