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NOVALIQ ANNOUNCES POSITIVE TOPLINE RESULTS FOR SECOND PHASE 3 TRIAL (ESSENCE-2) OF CYCLASOL® IN DRY EYE DISEASE

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, December 21, 2021 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced key results of the second pivotal Phase 3 trial (ESSENCE-2) evaluating the investigational drug CyclASol® for the treatment of dry eye disease (DED).

CyclASol® is a topical, anti-inflammatory and immunomodulating ophthalmic solution, containing 0.1% cyclosporine in EyeSol®, developed for the treatment of DED. The ESSENCE-2 trial is a multicenter, randomized, double-masked, vehicle-controlled clinical trial in 834 subjects to assess efficacy, safety, and tolerability of CyclASol® for the treatment of signs and symptoms of DED in patients not responding to artificial tears. ESSENCE-2 is the second pivotal trial and designed to replicate ESSENCE-1, a multicenter, randomized, double-masked, vehicle-controlled clinical trial in 328 subjects in the same indication.

CyclASol® demonstrated superior effects over its vehicle on the primary sign endpoint, improvement of total corneal fluorescein staining (tCFS) at day 29 (p-value = 0.0278). The vast majority of patients receiving CyclASol® (71.6%) responded within four weeks with a clinically meaningful improvement of ≥3 grades in total corneal staining. The proportion of responders was significantly higher compared to vehicle-treated patients (p = 0.0002). Responders showed also statistically significant improvements in a variety of symptoms compared to non-responders at day 29.

All key prespecified objective sign endpoints such as conjunctival staining, proportion of central corneal staining responders, and Schirmer responders (≥10mm), showed clinically meaningful improvements and statistical significance over vehicle with an early onset of action starting after two weeks of dosing.

CyclASol® demonstrated clinically relevant improvement over baseline for a variety of subjective symptom endpoints. The analysis for the primary, subjective symptom endpoint at day 29, Eye Dryness Score (VAS), showed that the improvement in CyclASol® was comparable to vehicle.

The safety and tolerability of CyclASol® was further confirmed in the ESSENCE-2 trial. The number of all adverse events (AEs) and ocular AEs, including instillation site reactions, were low. AEs were generally of mild intensity and similarly distributed between the two treatment groups. The drop comfort score showed excellent tolerability and was notably comparable in both treatment groups. More than 75% of

patients rated their satisfaction with the CyclASol® treatment positive or neutral at the end of the 4-week ESSENCE-2 trial.

“These results are extremely encouraging. Based upon two Phase 3 studies CyclASol® has the potential to treat both, the clinical signs and symptoms of dry eye disease.,” said John D. Sheppard, MD, MMSc, FACS, professor of ophthalmology at Eastern Virginia Medical School, and Mid-Atlantic Medical Director for Eye Care Partners. “A clean tolerability profile with a rapid onset of action are attributes of the water-free EyeSol® technology offering the most novel vehicle in eye care.”

The results of ESSENCE-2 are consistent with data from earlier studies, including the first pivotal phase 3 trial ESSENCE-1 [1] and the phase 2 trial [2], confirming that CyclASol® has the potential to become the most potent anti-inflammatory dry eye disease treatment with an early onset of action, excellent safety, tolerability, and eyedrop comfort.

Novaliq will discuss the ESSENCE-2 results and next steps to submit a New Drug Application (NDA) with the U.S. Food and Drug Administration in the near future. Novaliq will also work with the European Medicines Agency (EMA) and other regulatory agencies to initiate the regulatory approval process in geographies outside the U.S..

“Dry eye is a condition with a wide range of symptoms leading to chronic ocular surface damage and interfering with a patient’s vision and quality of life. Current treatment options have limitations. Prescribers and patients expect a fast acting and comfortable upon instillation drug addressing the root cause of the disease and being significantly better than OTC choices.”, said Dr Christian Roesky, Chief Executive Officer Novaliq. “CyclASol®’s product profile has the potential to fill this therapeutic gap. We will continue to work with regulatory authorities worldwide to make this innovation available to millions of patients suffering from this ocular disease.”

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 and hyperosmolarity, inflammation and damage of the ocular surface tissues, the corneal and conjunctival cells. Intrinsic and extrinsic factors cause stress to the ocular surface, which accelerate the cycle and, in turn, exacerbate dry eye.[3]

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 corneal staining, as shown in clinical trials, differentiates CyclASol® from existing therapies and are published in Cornea: The Journal of Cornea and External Disease.[1] 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. [2] 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 EyeSol®, the worldwide first water-free technology. EyeSol® is Novaliq's proprietary water-free technology using 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 an 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.

References

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