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NOVALIQ SUBMITS NEW DRUG APPLICATION SEEKING APPROVAL FOR FIRST-OF-A-KIND DRY EYE DISEASE TREATMENT CYCLASOL®

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, August 09, 2022 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for CyclASol® (cyclosporine ophthalmic solution), a proposed novel treatment for the signs and symptoms of dry eye disease (DED).

CyclASol® has demonstrated in two pivotal studies fast onset of therapeutic effect in the indication, clinical meaningful improvement of ocular surface damage, and excellent tolerability. Results from a 12-month long-term study confirmed that the effects are maintained, and even improved for most sign and symptom endpoints.

“This is the first submission of a novel product category of water-free topical drug therapies utilizing EyeSol® as a drug carrier”, said Christian Roesky, Ph.D., CEO, Novaliq. “CyclASol® is a first-of-a-kind drug therapy and aims to expand treatment success for patients with dry eye disease and their eye care professionals. If approved by the FDA, CyclASol® addresses important unmet medical needs in DED through its ocular surface healing effect combined with high comfort of administration.”

Dry eye is one of the most common ocular surface disorders, with approximately 18 million Americans diagnosed with DED.[1,2] Inflammation and immunologic processes play a key role in the pathology of the disease.

A compromised ocular surface secondary to DED may also compromise refractive measurements before keratorefractive and phacorefractive surgeries and adversely impact expected visual outcomes after these surgeries.[3,4] The impact of the corneal surface damage secondary to DED on visual function is an underestimated aspect of the disease. Multiple guidelines recommend treatment of the corneal surface damage prior to ocular procedures. A high unmet need remains for better tolerated drugs with an early onset of therapeutic effect, which are compelling to be used and prescribed.[5,6]

“We are very proud to see another product rapidly moving to the market, which marks yet another important inflection point and milestone in Novaliq’s growth trajectory”, said Dr. Mathias Hothum, board member and managing director of dievini. “We are currently evaluating the commercialization strategies which includes talking to interested parties.”

About CyclASol®

CyclASol® is a first-of-a-kind topical treatment of cyclosporine, a potent anti-inflammatory and selective immunomodulatory drug. Whilst not water-soluble, cyclosporine is soluble in the EyeSol® excipient perfluorobutylpentane allowing for its improved bioavailability and better efficacy on the target tissue. The product contains no oils, no surfactants and is preservative-free due to the novel carrier. This provides additional clinical benefits for patients, such as improved tolerability and decreased visual disturbances.

The NDA is supported by safety and efficacy results in over 1,000 patients with DED from a Phase 2 dose finding study, the Phase 2b/3 ESSENCE-1 study, the Phase 3 ESSENCE-2 study and its open label extension study.[7,8]

CyclASol® has demonstrated in two independent adequate and well-controlled, multicenter studies (ESSENCE-1 and ESSENCE-2) clinically meaningful and statistically significant improvements in the indication.

Effects on the ocular surface include a statistically significant reduction in total corneal fluorescein staining (tCFS) score favoring CyclASol® in both studies at Days 15 and 29. Up to 71.6% of patients responded within four weeks with a clinically meaningful improvement of ≥ 3 grades in total corneal staining. This proportion of responders was significantly higher compared to vehicle-treated patients in both studies. Responders showed also statistically significant improvements in a variety of symptoms compared to non-responders at day 29. The ASCRS guidelines recognize corneal staining as the single most important clinical sign of DED as it indicates the level of epithelial damage and visual impairment, and if left undertreated, DED can become chronic and more difficult to treat.[3]

Effect on tear production: In both studies, compared to vehicle at the end of treatment, there was a statistically significant ($p<0.05$) higher percentage of patients with increases of ≥ 10 mm from baseline in Schirmer's tear test score at Day 85 and Day 29, respectively, confirming a known effect of the active ingredient cyclosporine. Meeting this endpoint in two independent studies is clinically meaningful on its own and considered to demonstrate efficacy for the treatment of signs and symptoms of DED.

Head-to-head data versus Restasis™ from the phase 2 study suggest that CyclASol® has a stronger and faster therapeutic effect on the ocular surface.[8]

Maintenance of effect results from the long-term study CYS-005 confirmed that the effect of CyclASol® was maintained, and even improved for most endpoints, over the 52-week treatment period.

Safety and Tolerability: Tolerability of CyclASol® was shown by high drop comfort patient ratings in both studies. The most common adverse reaction observed was instillation site reactions, which was reported in 8.1% of patients in the pooled studies. These were in all but one case mild. The only other adverse reaction reported in > 2% of the patients was visual acuity reduced (2.7%).

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.

In July 2022 submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) was announced seeking approval for NOV03 (perfluorohexyloctane), for the proposed indication of treating the signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD). In addition to CyclASol®, the company continues to progress multiple additional pipeline opportunities based on its validated EyeSol® platform, both in ophthalmology and adjacent indications like dermatology.

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.

Recommended Readings

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