Novaliq Provides Development Update on CyclASol Topical Ophthalmic Solution for the Treatment of Dry Eye Disease

HEIDELBERG, GERMANY, July 23, 2020 /EINPresswire.com/ -- Novaliq GmbH, a pharmaceutical company focusing on first- and best-in-class ocular therapeutics, today provided a development update on its investigational water-free and preservative-free drug CyclASol®.

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> *John D. Sheppard, MD, MMSc, FACS*

- CyclASol has the potential to change the way eye care practitioners treat patients with dry eye disease
- EyeSol®, the unique water-free technology, unfolds the full potential of cyclosporine A on the ocular surface with an unprecedented tolerability profile
- Novaliq agreed with the U.S. Food and Drug Administration (FDA) that the second registrational trial, ESSENCE-2, is expected to complete the clinical development of CyclASol®
- ESSENCE-2 is a multicenter, randomized, double-masked, vehicle-controlled clinical trial expected to start in the second half of 2020

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 increases residual time on the ocular surface and enables a high bio-availability in the target tissues to unfold the full potential of cyclosporine A. The multi-dose, preservative-free, smaller and more physiologic droplet size profile provides unique clinical benefits and outstanding tolerability. Notably, the improvement in visual function associated with a clinically significant reduction of corneal staining, as shown in the recent Phase 2/3 clinical ESSENCE-1 trial, will differentiate CyclASol® from existing therapies.

"CyclASol® thrusts a reinvigorated cyclosporine A into first-line therapy for every eye care practitioner who treats dry eye disease," said John D. Sheppard, MD, MMSc, FACS, professor of ophthalmology at Eastern Virginia Medical School and president of Virginia Eye Consultants, a CVP partner practice. "An unprecedented tolerability profile with a rapid onset of action is attributable to the EyeSol® technology offering the most novel vehicle in eye care. CyclASol® treats both the clinical signs and symptoms of dry eye disease. Furthermore, demonstrated improvements in visual function address an economically and societally important unmet clinical

need for millions of diagnosed but untreated or undertreated patients."

The CyclASol® development plan and clinical trial design have been agreed upon by the U.S. Food and Drug Administration (FDA) in an end-of-phase 2 meeting. The FDA concurred with the company that the replication of the ESSENCE-1 results on clinical signs and patient reported symptoms is sufficient clinical evidence to support a New Drug Application (NDA) filing in the indication.

The planned 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. Novaliq has awarded Ora, Inc., the world's leading full-service ophthalmic clinical research organization (CRO), with conducting the trial, which is expected to start in the second half of 2020 with approximately 835 subjects at approximately 25 U.S. clinical centers. The pre-specified primary endpoints of the trial are the change from baseline in total corneal staining and the eye dryness score at day 28. Importantly, the trial will include the assessment of reading speed as an objective and quantifiable measurement of visual function.

Dry eye disease (DED) is a multifactorial and complex disease of the ocular surface.[1] Currently more than 16 million Americans are diagnosed with DED while approximately only 2 million patients are receiving treatments.[2] The majority of diagnosed DED patients fail to get a satisfactory response with current treatments. Over 60% of patients using currently approved drug therapies in the U.S. discontinue their treatment within 12 months of initiation. In particular, local intolerabilities are considered a key reason for the high discontinuation rates.[3] [4]

In addition to dryness-related symptoms, impairment of visual function plays a significant role in the reduction of work productivity and patients' health-related quality of life. Recent investigations and evidence reveal the influence and high relevance of cornea and ocular surface damage on visual symptoms that affect functions such as reading, looking at screen displays, driving and night vision.[5]–[8]

Results from the previous Phase 2/3 ESSENCE-1 clinical trial demonstrated statistically significant improvements with CyclASol® in both sign and symptom endpoints as compared to its vehicle. Additionally, the trial demonstrated that reading speed improves with corneal staining reduction and the subjects' perceived reading improvement was mirrored by the measured improvement of reading speed. Safety and tolerability in the trial were excellent with outstanding comfort scores reported, comparable with comfort scores of lubricating eye drops.

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 are closely monitoring the situation and will 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 eye drop technology. Novaliq offers an industry-leading portfolio addressing today's unmet medical need of millions of patients with eye diseases. Novaliq is headquartered in Heidelberg, Germany and 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.

Sources:
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