Novaliq Announces First Patient Randomized in Its ESSENCE Phase 2b/3 Trial of CyclASol® for the Treatment of the Signs and Symptoms of Dry Eye Disease

- ESSENCE Phase 2b/3 Trial Commences with First Patient Randomized in U.S.
- Top Line Data Expected Third Quarter 2018
- CyclASol® May Overcome the Intolerability Profiles of Current Treatments Due to the Benefits of a Water-free Vehicle and Its Mechanism of Drug Delivery

HEIDELBERG, Germany—(BUSINESS WIRE)—Novaliq GmbH, a specialty pharmaceutical company with a disruptive drug delivery platform that transforms poorly soluble drugs into effective therapeutics for ophthalmology, today announced that it has begun randomization of patients in its ESSENCE Phase 2b/3 clinical trial that will evaluate CyclASol® for the treatment of the signs and symptoms of dry eye disease (DED).

DED is a multifactorial and complex disease of the ocular surface. Ocular surface inflammation and autoimmune dysregulation play a key etiological role in the development of DED. In the U.S. alone, an estimated >16 million people suffer from DED¹. This patient population is highly underserved as there are only a few approved drugs in select key markets.

CyclASol® is a preservative free ophthalmic solution of cyclosporine A in EyeSol®, Novaliq’s proprietary and first and only water-free technology. Excellent safety and tolerability of CyclASol® as well as the ability to improve signs and symptoms of DED with an early onset of effect have been demonstrated in a previous Phase 2 study. The results of this Phase 2 study are being presented [PO059] at AAO 2017, the American Academy of Ophthalmology’s 121st annual meeting, which takes place November 11-14, 2017 in New Orleans. CyclASol® potentially overcomes the current intolerance and efficacy profiles due to the benefits of a water-free vehicle and the mechanism of drug delivery.

“Medications with highly favorable tolerability profiles and early onset of action are an unmet medical need in dry eye disease,” said John Sheppard MD, Professor of Ophthalmology, Eastern Virginia Medical School. “Based on the very promising data from the CyclASol® Phase 2 study, we are excited to participate in the ESSENCE trial, thereby moving this promising product closer to the market.”

Novaliq’s ESSENCE 2b/3 clinical trial (NCT03292809) is a randomized, double-masked, vehicle-controlled, multi-center trial, designed to evaluate the safety, efficacy and tolerability of topical CyclASol® for the treatment of DED. Study patients will be randomized to one of two treatment groups: CyclASol® and vehicle. ESSENCE has a primary efficacy endpoint at 4 weeks with continued dosing for safety evaluation over a total of 3 months. The study is being conducted in approximately 10 sites in the U.S., with a total planned enrollment of approximately 316 patients.

“The initiation of this phase 2b/3 trial of the CyclASol® program is a major milestone in advancing our clinical development of CyclASol®,” says Sonja Krösser, PhD, VP Clinical Development at Novaliq GmbH. “This pivotal trial design has been based on sound prior data demonstrating superior reduction of corneal and conjunctival staining as well as OSDI® of CyclASol® over its vehicle in the population selected for ESSENCE. This trial is designed to support planned regulatory applications worldwide, including the United States, Europe and Japan.”

About Novaliq – Novaliq GmbH, founded in 2007, is a Heidelberg based specialty pharmaceutical company focused on ophthalmology. Its mission is to transform poorly soluble drugs into effective ocular therapeutics for both the front and the back of the eye. Novaliq’s proprietary EyeSol® technology enhances the topical bioavailability, stability and safety of traditionally insoluble or unstable drugs improving the delivery, efficacy and convenience of treatments for ocular surface diseases including dry eye through preservative free and multi...
dose formulations. Novaliq has developed a tiered and long-term sustainable dry eye family of truly differentiated products that addresses the different needs of dry eye patients. Novaliq’s most advanced product is NovaTears® with CE-approval marketed under the brand name EvoTears® in Europe. CyclASol® a second-generation prescription drug is currently in preparation for a pivotal trial. More on www.novaliq.com.

Source:

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