Unique Drug And Oxygen Delivery Systems

NOVALIQ

FOR IMMEDIATE RELEASE

NOVALIQ BEGINS PHASE 2 CLINICAL TRIAL OF CYCLASOL® FOR THE TREATMENT OF MODERATE TO SEVERE DRY EYE DISEASE

Heidelberg, Germany – February 16th, 2016 – Novaliq GmbH, a pharmaceutical company with a disruptive drug delivery platform that transforms poorly soluble drugs into effective therapeutics for ophthalmology, today announced that it has begun enrolling patients in a Phase 2 clinical trial that will evaluate the safety, efficacy and tolerability of CyclASol® for the treatment of moderate to severe dry eye disease (DED). CyclASol is a clear, preservative free ophthalmic solution of cyclosporine in SFA (semifluorinated alkanes).

This Phase 2 study is a randomized, double-masked, placebo-controlled, multi-center trial, designed to evaluate the safety, efficacy and tolerability of topical CyclASol for the treatment of moderate to severe DED. Patients will be randomized to one of four treatment groups that include two CyclASol groups, a placebo (vehicle control) group and an open label cyclosporine A 0.05% ophthalmic emulsion group. Study subjects will self-administer one drop twice daily, returning for examination periodically and at the end of the trial at four months. The study is being conducted in approximately 4 sites in the U.S., and total planned enrollment is 200 patients.

“CyclASol is differentiated from other cyclosporine containing treatments for dry eye due to its innovative vehicle.” said George Ousler, vice president of Dry Eye at Ora, Inc. “In a murine model of DED, CyclASol was shown to be at least equally effective but with a significantly faster therapeutic response compared to commercially available cyclosporine and dexamethasone products. Furthermore, the clinical phase 1 data has demonstrated excellent tolerability.”

"The initiation of this Phase 2 trial is an important step in advancing our clinical development plan," says Bernhard Günther, managing director and CEO of Novaliq GmbH. “In 2015, we made our footprint in the OTC dry eye market with the successful European launch of NovaTears®. Given the lack of treatment options currently available for patients with more severe DED, there is a need for novel, non-blurring, non-irritating, and preservative- and water-free formulations.

About Novaliq – Novaliq GmbH, founded in 2007, is a Heidelberg based specialty pharmaceutical and drug delivery company with the mission to transform poorly soluble drugs into effective ocular therapeutics for both front and back of the eye. Novaliq’s proprietary EyeSol® technology enhances the topical bio availability, 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’s most advanced product is NovaTears with CE-marking based on Novaliq’s proprietary EyeSol Technology. NovaTears is marketed under the brand name EvoTears™ in Europe. **More on www.novaliq.com**.

# # #

Contacts Europe
Bernhard Günther: + 49 6221 502 5911
Managing Director, CEO
Novaliq GmbH
info@novaliq.de

Oliver Schlüter, PhD: + 49 6221 502 59155
Managing Director, CFO
Novaliq GmbH
info@novaliq.de

Contact USA
Michael O’Rourke + 1 813 323 1438
Scotia Vision Consultants
scotiavc@gmail.com