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NOVALIQ ANNOUNCES POSITIVE TOPLINE RESULTS FOR ITS SEECASE PHASE 2 TRIAL OF NOV03 FOR THE TREATMENT OF PATIENTS WITH DRY EYE DISEASE

- The SEECASE trial met its prespecified primary endpoint for both treatment schedules at 8 weeks
- The trial further demonstrated pronounced improvements in a number of symptoms with statistical significance at all timepoints
- NOV03 is the first drug targeting evaporative dry eye disease associated with meibomian gland dysfunction

Heidelberg, Germany – Oct 24, 2018 – Novaliq, a specialty pharmaceutical company for the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology for ophthalmology, today announces positive topline results for its SEECASE phase 2 clinical trial of NOV03 for the treatment of dry eye disease (DED) in more than 300 patients.

NOV03 (100% perfluorohexyloctane) is a preservative-free ophthalmic solution and the first drug developed to treat evaporative DED associated with meibomian gland dysfunction (MGD). Patients suffering from DED with imbalanced tear conditions due to significant MGD represent a symptomatic and large population with high medical needs in today's clinical care.

Currently, the treatment options for these patients are limited. NOV03 uniquely treats DED associated with MGD based on novel modes of action that complementary balance the tear condition: it stabilizes the lipid layer for several hours, thereby preventing excessive evaporation, and it has the potential to penetrate the meibomian glands, to improve meibum quality, and to enhance the function of the meibomian gland.

Since January 2018, Novaliq has conducted the SEECASE phase 2 clinical trial which enrolled 336 patients at ten clinical sites in the United States. SEECASE was a phase 2, multi-center, randomized, double-masked, saline-controlled clinical trial (NCT03333057) and was designed to evaluate the effects of NOV03 at two different dosing regimens on signs and symptoms of DED. SEECASE evaluated its primary efficacy at eight weeks.

The SEECASE trial met its prespecified primary endpoint, improvement of total corneal fluorescein staining over control at eight weeks, with high statistical significance for both dosing regimens QID and BID ($p<0.001$ and $p=0.009$, respectively). The effect started as early as two weeks after start of treatment and was maintained over the entire duration of the trial for both treatment regimens. In addition, NOV03 showed pronounced and highly statistically significant improvement in various symptoms over control, again consistent over the entire duration of the trial. The magnitude of effect in symptoms is on average up to 50% improvement from baseline depending on the parameter and thus highly relevant for DED patients.

"I am impressed by the strong data of the SEECASE trial. The simultaneous demonstration of improvement in symptoms and robust improvement in ocular surface signs stands out as among the most convincing data in a dry eye study that I have seen," said Joseph Tauber, MD, and practicing ophthalmologist at Tauber Eye Center, Kansas City, MO. "A treatment that could effectively relieve the symptoms of many patients with DED associated with meibomian gland dysfunction, for which there are currently poor treatment options, would be a very welcome addition to our clinical practice."

The study showed an excellent safety and tolerability profile for NOV03 and thus provides robust data to support its development as a first treatment targeting patients with predominantly evaporative DED associated with MGD.

“We are very pleased with the outcomes of the SEECASE study showing unprecedented sign and symptom improvements for patients with evaporative DED associated with MGD,” says Sonja Krösser, PhD, VP Clinical Development at Novaliq. “We look forward to discussing our data with the FDA and to agreeing on next steps to timely complete the clinical development of NOV03.”

Details of the topline results of SEECASE will be presented for the first time by Novaliq’s CEO, Christian Roesky, during the Ophthalmology Innovation Summit (OIS) on October 25th, 2018 in Chicago, USA. For further information, please send an email to event@novaliq.com.

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 technology for ophthalmology products. With an initial focus on dry eye disease (DED), Novaliq offers an industry-leading portfolio addressing today’s unmet medical needs of millions of patients with eye disease. Novaliq’s lead assets in late-stage clinical development are:

- CyclASol®, an anti-inflammatory and immunomodulating drug for the treatment of DED with a demonstrated early onset of action and an excellent tolerability
- NOV03, the first drug addressing evaporative DED associated with meibomian gland dysfunction (MGD)

NovaTears® water-free eye drops for dry eye disease have CE certification and are commercialized in Australia/New Zealand by AFT Pharmaceuticals and in Europe as EvoTears® by Ursapharm.

Novaliq is headquartered in Heidelberg, Germany and has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech Holding, an active investor in Life and Health Sciences companies. More on **www.novaliq.com**.

About Dry Eye Disease

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 only two million patients are receiving treatments [2]. The patient population with evaporative DED accounts for 61-90% of all DED patients [3,4]. There are limited treatments available and the majority of patients fail to get a satisfactory response.

Sources:

1. Craig et al., TFOS DEWS II Definition and Classification Report. *Ocul Surf* 2017, 15:276-283.
2. Ocular Drug Delivery Report, MCD Group, July 2017.
3. Lemp et al.; *Cornea* 2012, 31: 472–8.
4. Bron et al.; *Ocul Surf* 2004, 2:149-164.

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Media contact:

Heidrun Kirsch
VP Marketing, Novaliq GmbH
media@novaliq.com