

Novaliq named Finalist in “Clinical Trial Result of the Year” category of the Clinical & Research Excellence Awards CARE 2019

- Novaliq is recognized for its SEECASE clinical trial results of NOV03 demonstrating unprecedented sign and symptom improvements for Dry Eye Disease (DED) patients while offering an excellent safety profile
- NOV03 is potentially the first drug targeting the key underlying cause of evaporative DED, the leading reason for this undertreated disease that impacts visual function

Heidelberg – February 26, 2019 - Novaliq, the pharmaceutical company for the development and commercialization of first- and best-in-class ocular therapeutics based on the water-free EyeSol® technology, has been named a finalist in “Clinical Trial Result of the Year” category of the CARE Awards, which recognizes outstanding work across the global clinical research enterprise.

In 2018, Novaliq conducted the SEECASE trial which enrolled 336 patients at ten clinical sites in the United States and published topline data in October 2018. SEECASE was a phase 2, multi-center, randomized, double-masked, controlled clinical trial (NCT03333057) and was designed to evaluate the effects of two dosing regimens of NOV03 on signs and symptoms of Dry Eye Disease (DED). The trial results showed that NOV03 effectively improved both clinical signs of ocular health and patient-reported symptoms, with a fast onset of action, in patients with DED associated with MGD.

NOV03 is a potential breakthrough therapy for DED patients based on its novel mode of action. NOV03 stabilizes the lipid layer of the tear film and thereby prevents excessive tear evaporation, and also penetrates meibomian glands, potentially dissolving thickened meibum to improve meibomian gland function. It is therefore the first time that a drug addresses the underlying cause of evaporative DED.

Based on the unprecedented findings from the SEECASE trial, Novaliq has accelerated its development program to achieve regulatory approval and drug availability on the market soon. The final pivotal clinical trial is expected to start in 2019, leading to the NDA filing in 2021.

The CARE Awards 2019 features 11 categories, significant accomplishments and highlight innovation across the industry – from rare diseases drug development and patient centricity in trials and research, to product and technological development, clinical results and collaborative efforts between individuals, departments, or companies. Entries are judged independently by a panel of experts from all core sectors of the clinical R&D industry.

“We are thrilled to be selected as one of three finalists for the clinical trial results of the SEECASE trial and thus be acknowledged for the dedicated work of Novaliq’s clinical development team lead by Sonja Krösser, PhD, VP Preclinical & Clinical Development. This worldwide recognition of the trial outcomes is reflecting the high potential of NOV03 eye

drops to impact the lives of many untreated patients suffering from dry eye disease and further supports Novaliq's strategy to accelerate the last phase of development," said Gabriela Burian MD, Consulting Chief Medical Officer at Novaliq.

The 2019 winners will be announced at a ceremony on Thursday, May 2nd at the Hyatt Regency Boston, MA, where distinguished leaders in the biopharmaceutical, CRO, and diagnostic industries gathered from all corners of the globe.

You can view the full list of finalists here:

<https://pharmaintelligence.informa.com/events/awards/care-awards-2019/shortlist>

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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 first water-free technology worldwide 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. [NOV03](#) and CyclASol[®] are the two late stage development compounds. NOV03 is the first drug developed to treat evaporative DED associated with meibomian gland dysfunction in a highly effective way. CyclASol[®], an ophthalmic solution of 0.1% cyclosporine A in EyeSol[®], is an anti-inflammatory and immunomodulating drug for the treatment of aqueous deficient DED. Both compounds have shown superior clinical benefit, with an onset of action and an excellent tolerability profile.

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.

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