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NOVALIQ RECEIVES FDA IND CLEARANCE TO ADVANCE NOV05 IN A PHASE II CLINICAL TRIAL IN NON-INFECTIOUS ANTERIOR UVEITIS

- Study could lead to first-ever topical steroid-free treatment for the inner eye disease non-infectious anterior uveitis (NIAU)
- The study builds on ocular pharmacokinetic models demonstrating delivery after topical application and on animal models of experimental uveitis demonstrating pharmacological effects
- Novaliq is expanding with this proof-of-concept study into retina and inner-eye diseases as targeted topical delivery of EyeSol®-based drugs allowing to develop breakthrough therapies

HEIDELBERG, Germany and CAMBRIDGE, MA, USA, January 26, 2026 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on its unique water-free EyeSol® drug category, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for NOV05, the company's first IND for treating inner-eye diseases.

NOV05, tacrolimus ophthalmic solution in EyeSol®, is a unique, steroid-free topical anti-inflammatory treatment. The IND clearance enables initiation of the EYETAC Phase II clinical trial in patients with non-infectious anterior uveitis (NIAU).

Anterior uveitis is an inflammation of the inner eye including the iris and ciliary body, that typically causes a red, painful, light-sensitive eye and can lead to vision loss if not treated promptly. NIAU represents 67-90% of uveitis cases in the developed world.[1]

To treat uveitis a drug must reach the uveal tract inside the eye. Current treatment choices are limited to corticosteroid eye drops and, if insufficient or the inflammation is more severe, periocular or intraocular corticosteroid injections and systemic immunosuppressive agents are applied, all of which are known to be associated with complications.[2]

Oral tacrolimus was shown effective but has low bioavailability in eye tissues and systemic side effects limit its use. Delivery of topical tacrolimus to the tissues inside the eye has not been shown yet.

"The IND clearance of the EYETAC study is a major milestone on our strategic expansion to retina and diseases of the inner-eye using targeted topical delivery of EyeSol® based drugs," said Dr. Christian Roesky, Chief Executive Officer Novaliq. "A steroid-free eye drop that effectively controls intraocular inflammation, without associated side effects, is an unmet medical need currently in patients with NIAU and that could be addressed with NOV05. Furthermore, the study aims to demonstrate a general proof of delivery of active ingredients to the back of the eye tissues using EyeSol®, which would allow us to develop multiple topical EyeSol® therapies for retina diseases."

EYETAC is a phase 2, randomized, double-masked clinical trial (NCT #07285070) conducted at clinical centers in the United States of America, in patients with active NIAU, evaluating two concentrations of tacrolimus, and is expected to begin in the first quarter of 2026. The study aims to evaluate the safety and tolerability of NOV05 and to assess the potential dose-dependent clinical anti-inflammatory effect. The clinical study is based on the prior ocular pharmacokinetics findings demonstrating delivery of

tacrolimus to ocular tissues after topical application in two species[3], the demonstration of pharmacological effect in two independent animal models of experimental uveitis[4], and the successful toxicology study[4].

About Novaliq

Novaliq is a private biopharmaceutical company focusing on the development of first- and best-in-class ocular therapeutics. Novaliq developed EyeSol®, a novel drug category of water-free topical eye medicines. Two FDA-approved EyeSol® medicinal products for dry eye disease – Miebo® and Vevye® - are on the market in the US and have transformed patient care. The Novaliq R&D pipeline provides multiple development opportunities in ophthalmology and retina therapies. Novaliq is headquartered in Heidelberg, Germany and has an office in Cambridge, MA, USA. The long-term single shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on www.novaliq.com.

Recommended Readings

1. *Joltikov KA, Lobo-Chan AM. Epidemiology and Risk Factors in Non-infectious Uveitis: A Systematic Review. Front Med (Lausanne). 2021 Sep 10;8:695904.*
2. *Wu X, Tao M, Zhu L, Zhang T, Zhang M. Pathogenesis and current therapies for non-infectious uveitis. Clin Exp Med. 2023 Aug;23(4):1089-1106*
3. *Kroesser S, Korward J, Sheppard JD, Perez VP. Ocular distribution of Tacrolimus after topical administration as EyeSol formulations in rabbits and dogs. Investigative Ophthalmology & Visual Science June 2025, Vol.66, 652 and ARVO 2025 poster*
4. *Novaliq data on file.*

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