Novaliq Media Contact:
Simone Angstmann-Mehr
info@novaliq.com

Laboratoires Théa Media Contact:
Julie Ahmed
julie.ahmed@theapharma.com

NOVALIQ AND LABORATOIRES THÉA ANNOUNCE PARTNERSHIP AND EU APPROVAL FOR VEVIZYE® (CICLOSPORIN 0.1% EYE DROPS SOLUTION)

HEIDELBERG, Germany, CAMBRIDGE, MA, USA, and CLERMONT-FERRAND, France, October 2, 2024 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, and Laboratoires Théa (Théa), the leading independent eye care group in Europe, announce European Commission approval of Vevizye® (ciclosporin 0.1% eye drops solution) in Europe and the closing of a partnership under which Théa has acquired the rights to commercialise the product in Europe and selected countries in the Middle East and North Africa (MENA).

Vevizye® is based on Novaliq's proprietary EyeSol® technology and the only water-free ciclosporin 0.1% eye drops solution approved in the European Union for the treatment of moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients which has not improved despite treatment with tear substitutes.

"Our partnership with Novaliq highlights our dedication to delivering innovative treatments to all patients.", stated Jean-Frédéric Chibret, President of the Théa Group. "We are looking forward to launching Vevizye® to complement our range of non-preserved treatments for dry eye, a disease that has substantial impacts on the quality of life of many patients."

Dry eye disease (DED) is one of the most common ocular surface disorders, affecting approximately 15 million diagnosed patients in the five largest European countries[(1)] and is difficult to treat[(2)]. In Europe, there is a need for additional prescription treatments intended for adults suffering from moderate to severe dry eye disease.

"We are thrilled to partner with Théa, the leading ophthalmic pharmaceutical company in Europe, to bring Vevizye® to patients. Théa's focus on innovation, its leading commercial capabilities and the strong track record in Europe makes them the perfect partner for Novaliq" said Christian Roesky, Ph.D., Chief Executive Officer Novaliq.

About ESSENCE 1[(3)] & ESSENCE 2[(4)] clinical studies

The efficacy of Vevizye® for the treatment of dry eye disease was demonstrated by two randomised, multicentre, double-masked, vehicle-controlled studies (ESSENCE-1[(3)] and ESSENCE-2[(4)]).

The change from baseline in total corneal fluorescein staining (tCFS) score at Day 29 was the primary endpoint in both trials. At Day 29, a statistically significant reduction in tCFS favouring Vevizye® was observed in both studies. Up to 71.6% of patients responded within four weeks with a clinically improvement in total corneal fluorescein staining. All other key secondary ocular surface sign endpoints (tCFS at Day 15, conjunctival staining at Day 29 and central corneal staining at Day 29) showed statistically significant effects favouring Vevizye® in both studies. Continued improvement under therapy in both signs and symptoms of DED were demonstrated over a period of up to 56 weeks.[(5)]

About VEVIZYE®

The product was approved by the US Food and Drug Administration (FDA) in May 2023 as VEVYE®.

In the European Union (EU) the eligibility to the centralised procedure under Article 3(2)(b) of Regulation (EC) No 726/2004 was based on the "interest of patients". Vevizye® is indicated for the treatment of moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients, which has not improved despite treatment with tear substitutes. Vevizye® is approved in all 27 EU member states.

Full European Summary of Product Characteristics for Vevizye® *is available from the EMA website at www.ema.europa.eu . At time of publication of this press release, the full SPCs have not been yet published online.*

Additional regulatory applications are under review in several countries, including China, Australia, and New Zealand.

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 are beginning to revolutionize 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.

About Laboratoires Théa

Théa is the leading independent European pharmaceutical company specialized in the research, development, and commercialization of eye care products. Based in Clermont-Ferrand, France, this family-owned and run company comprises more than 2,000 collaborators and has expanded by opening more than 35 affiliates and offices in Europe, North Africa, North and South America, and the Middle East. Its products are available in 75 countries. In 2023, Théa's turnover reached €923 million. More on www.laboratoires-thea.com.

Recommended Readings

1. Global Data. Dry Eye Syndrome: Seven-Market Drug Forecast and Market Analysis Update | December 2022
2. Jones et al. TFOS DEWSII Management and Therapy Report. The Ocular Surface. 2017; 15 (3): 575-628
3. Sheppard et al. A Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase 2B/3 ESSENCE Study. Cornea. 2021 Oct 1;40(10):1290-1297
4. Akpek et al. Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease The ESSENCE-2 Randomized Clinical Trial. JAMA Ophthalmology. 2023; 141(5):459-466
5. Wirta et. al. Long-Term Safety and Efficacy of a Water-Free Cyclosporine 0.1% Ophthalmic Solution for Treatment of Dry Eye Disease: ESSENCE-2 OLE. Cornea. 2024 May 21.

Any product/brand names and/or logos are trademarks of their respective owners.
© 2024 Novaliq GmbH, Heidelberg, Germany and Laboratoires Théa S.A.S., Clermont-Ferrand, France. All rights reserved.