

SENJU PHARMACEUTICAL AND NOVALIQ ENTER INTO LICENSE AGREEMENT FOR NOV03 (PERFLUOROHEXYLOCTANE OPHTHALMIC SOLUTION) FOR THE TREATMENT OF DRY EYE DISEASE IN JAPAN

Osaka, Japan & Heidelberg, Germany, and Cambridge, MA, USA, June 13, 2023 – Senju Pharmaceutical Co., Ltd., a researched-based Japanese pharmaceutical company focusing the field of ophthalmology, and Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on its unique EyeSol® water-free technology, are pleased to announce the closing of a license agreement on Japan rights to develop, manufacture, and commercialize NOV03 (perfluorohexyloctane ophthalmic solution), the first and only prescription treatment for signs and symptoms of dry eye disease that directly targets tear evaporation.

“We are thrilled to collaborate with Novaliq as a pioneer for cutting edge water-free eye drop technology. On the basis of very unique features and unparalleled clinical data of NOV03, we strongly believe that it will provide huge clinical benefits to Japanese patients”, said Shuhei Yoshida, President of Senju Pharmaceutical.

NOV03 is a first-in-class, preservative-free treatment for signs and symptoms of dry eye disease. Its unique mode of action directly targets tear evaporation by forming a monolayer at the air-liquid interface of the tear film. NOV03 has demonstrated safety and efficacy in the indication in multiple, adequately controlled studies in patients with a history of dry eye disease and clinical signs of Meibomian gland dysfunction.

In Japan, potentially more than 5 million patients are diagnosed with dry eye disease [1] and current treatment options addressing evaporative dry eye disease or dry eye associated with clinical signs of Meibomian gland dysfunction are limited.

“We are proud to partner with Senju Pharmaceutical, a leading ophthalmic company in Japan, to bring NOV03 to patients in Japan”, said Dr. Christian Roesky, CEO, Novaliq. “NOV03 offers a new and unique mode of action and is clinically validated. Its safety and efficacy have been demonstrated in numerous studies in Europe, United States and China. With approximately 10 million units sold in Europe and Australia since its launch in 2015, our water-free EyeSol® technology is proven to be safe and well accepted”.

Under the terms of the license agreement, Novaliq is eligible to receive upfront and milestone payments contingent upon the achievement of regulatory and sales milestones as well as royalties on net sales of NOV03 in Japan.

About NOV03 (perfluorohexyloctane ophthalmic solution)

NOV03 (perfluorohexyloctane ophthalmic solution) is a water-free, preservative-free eye drop being developed as a treatment for patients with dry eye disease associated with Meibomian gland dysfunction. It has a novel mode of action to stabilize the tear film lipid layer and thereby protects from excessive evaporation. In addition, it has been shown to penetrate into the Meibomian glands and

potentially liquify altered secretions. Four adequate and well controlled studies have demonstrated that NOV03 improves the signs and symptoms of dry eye disease in patients with clinical signs of Meibomian gland dysfunction and is very well tolerated [2-5]. NOV03 is a Food and Drug Administration (FDA) approved drug therapy in the USA for the treatment of the signs and symptoms of dry eye disease and in NDA review in China.

About Senju Pharmaceutical

Senju is a privately held, research-based Japanese pharmaceutical company that develops, manufactures, and commercializes a variety of innovative products, focusing on the field of ophthalmology to improve the health and quality of vision for people worldwide through the company's products.

The characters that comprise Senju's company name in Japanese language are "Sen" and "Ju", or "thousand" and "bringing happiness". Senju's mission is to improve the joy of living of people associated with the company through the development of original pharmaceutical products.

Senju is headquartered in Osaka, Japan and has its subsidiaries and representative offices around the world. More on www.senju.co.jp/english/.

About Novaliq

Novaliq is a private biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol[®], the worldwide first water-free technology, using ultrapure semifluorinated alkanes (SFAs) that are physically, chemically, and physiologically inert with excellent biocompatibility and a very good safety profile.

On May 18th, 2023, U.S. FDA approved MIEBO[™] (perfluorohexyloctane ophthalmic solution; formerly known as NOV03) followed by the approval of VEVYE[™] (cyclosporine ophthalmic solution, development name CyclASol[®]) 0.1% on May 30th, 2023. In the EU, perfluorohexyloctane is registered as a medical device to treat patients with dry eye disease since 2013. The company continues to progress into other ophthalmic indications based on its validated EyeSol[®] platform.

Novaliq GmbH is headquartered in Heidelberg, Germany and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term 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. Global Data. Dry Eye Syndrome: Seven-Market Drug Forecast and Market Analysis Update | December 2022
2. Tauber J, Wirta DL, Sall K, Majmudar PA, Willen D, Krösser S; SEECASE study group. A Randomized Clinical Study (SEECASE) to Assess Efficacy, Safety, and Tolerability of NOV03 for Treatment of Dry Eye Disease. *Cornea*. 2021 Sep 1;40(9):1132-1140
3. Tian L, Gao Z, Zhu L, Shi X, Zhao S, Gu H, Xu G, Wang L, Dai H, Zhang H, Jin X, Ma K, Xu Y, Ma L, Pei C, Ke B, Krösser S, Zhang Y, Jie Y. Perfluorohexyloctane Eye Drops for Dry Eye Disease Associated With Meibomian Gland Dysfunction in Chinese Patients: A Randomized Clinical Trial. *JAMA Ophthalmol*. 2023 Apr 1;141(4):385-392
4. Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for Dry Eye Disease Associated with Meibomian Gland Dysfunction: Results of the Randomized Phase 3 GOBI Study. *Ophthalmology*. 2023 May;130(5):516-524

5. Sheppard JD, Kurata F, Epitropoulos AT, Krösser S, Vittitow JL; MOJAVE STUDY GROUP. NOV03 for Signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction: the Randomized Phase 3 MOJAVE Study: NOV03 for Dry Eye Disease Associated With Meibomian Gland Dysfunction (69 characters; limit, 60). Am J Ophthalmol. 2023 Mar 20: S0002-9394(23)00098-3

Any product/brand names and/or logos are trademarks of the respective owners.

© 2023 Novaliq GmbH, Heidelberg, Germany.