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Bausch + Lomb and Novaliq Announce FDA Approval of MIEBO™ (Perfluorohexyloctane Ophthalmic Solution) for the Treatment of the Signs and Symptoms of Dry Eye Disease

MIEBO is the First and Only Prescription Eye Drop Approved for Dry Eye Disease that Directly Targets Tear Evaporation, Based on Consistent Results from Two Consecutive Pivotal Phase 3 Trials

VAUGHAN, Ontario, and HEIDELBERG, Germany, May 18, 2023 – Bausch + Lomb Corporation (NYSE/TSX: BLCO) (“Bausch + Lomb”), a leading global eye health company dedicated to helping people see better to live better, and Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in class ocular therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has approved MIEBO™ (perfluorohexyloctane ophthalmic solution; formerly known as NOV03), for the treatment of the signs and symptoms of dry eye disease (DED). MIEBO is the first and only FDA-approved treatment for DED that directly targets tear evaporation.

“Today’s FDA approval of MIEBO further advances DED treatment by addressing a significant unmet need for millions of people suffering with this disease,” said Brent Saunders, chairman and CEO, Bausch + Lomb. “We are proud to bring to market the first and only prescription eye drop approved in the United States for the treatment of DED that directly targets evaporation. We expect to make MIEBO commercially available in the second half of this year.”

DED affects millions of Americans and is one of the most common ocular surface disorders.¹ A leading cause of DED is excessive tear evaporation, which due to an altered tear lipid layer, is often associated with the clinical signs of Meibomian gland dysfunction (MGD). An unstable tear film triggers increased ocular surface desiccation, inflammation and damage to the ocular surface.^{2,3} MIEBO is designed to reduce tear evaporation at the ocular surface.^{4,5}

In GOBI and MOJAVE, two phase 3 pivotal clinical trials which enrolled more than 1,200 patients (randomized 1:1 to MIEBO or hypotonic saline) with a history of DED and clinical signs of MGD, MIEBO consistently met its primary clinical sign and patient-reported symptom endpoint.

“In the two pivotal clinical trials, MIEBO addressed the persistent and chronic nature of DED by providing sustained improvement in both the signs and symptoms of DED,” said Preeya Gupta, M.D., cornea and cataract surgeon, Triangle Eye Consultants, Raleigh, North Carolina. “Because MIEBO inhibits evaporation, it may be an appropriate treatment option for patients whose tear evaporation exceeds tear supply.”

“Tear evaporation, which is a leading driver of DED, presents a significant treatment challenge. With the approval of MIEBO, eye care professionals can now take a new approach to DED therapy with a first-in-class water- and preservative-free prescription treatment option that specifically addresses tear evaporation,” said Paul Karpecki, O.D., director, Cornea and External Disease, Kentucky Eye Institute, and associate professor, University of Pikeville, Kentucky College of Optometry.

MIEBO Clinical Data

The FDA approval of MIEBO™ was based on results from two 57-day, multi-center, randomized, double-masked, saline-controlled studies, GOBI and MOJAVE, which enrolled a total of 1,217 patients with a history of DED and clinical signs of MGD,^{6,7} a major cause of development and disease progression.⁸ An estimated 86% of people with DED have excessive tear evaporation whereby MGD is the major contributor.^{9,10}

In the GOBI and MOJAVE phase 3 pivotal studies, MIEBO met both primary sign and symptom efficacy endpoints. The two primary endpoints were change from baseline at week eight (day 57 ± 2) in total corneal fluorescein staining (tCFS) and eye dryness Visual Analog Scale (VAS) score. Patients experienced relief of symptoms as early as day 15 and through day 57 with statistically significant reduction in VAS eye dryness score favoring MIEBO observed in both studies. Additionally, at days 15 and day 57, a significant reduction in tCFS favoring MIEBO was observed in both studies.

The most common adverse reactions experienced with MIEBO were blurred vision (1.3-3%) and eye redness (1-3%).

Additional Executive Commentary

“Today’s FDA decision marks a tremendous milestone for Bausch + Lomb as MIEBO becomes our first prescription pharmaceutical eye treatment to be approved by the FDA since becoming an independent, publicly traded eye health company,” said Andrew Stewart, president, Ophthalmic Pharmaceuticals, Bausch + Lomb. “We are proud to further deliver on our promise to bringing innovative new options to help patients improve their treatment journey.”

“Bausch + Lomb is deeply committed to bringing forward medicines that address unmet medical needs, and MIEBO is a prime example of this commitment being realized,” said Yehia Hashad, M.D., executive vice president, Research & Development and chief medical officer, Bausch + Lomb. “We are extremely grateful to all of our collaborators, including trial patients, clinical investigators and our R&D team, for their tireless contributions to this important milestone.”

“We believe that MIEBO will address a significant unmet need for the many Americans who struggle with evaporative dry eye,” said Christian Roesky, Ph.D., CEO, Novaliq. “We are grateful to Bausch + Lomb for their continued collaboration in bringing this unique new treatment option to market.”

INDICATION

MIEBO™ (perfluorohexyloctane ophthalmic solution) is used to treat the signs and symptoms of dry eye disease.

IMPORTANT SAFETY INFORMATION

- Patients should remove contact lenses before using MIEBO™ and wait for at least 30

minutes before reinserting.

- It is important for patients to use MIEBO exactly as prescribed.
- It is not known if MIEBO™ is safe and effective in children under the age of 18.
- The most common eye side effect seen in studies was blurred vision (1% to 3 % of patients reported blurred vision and eye redness).

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call [1-800-FDA-1088](tel:1-800-FDA-1088).

Click [here](#) for full Prescribing Information for MIEBO.

About Novaliq

Novaliq is a 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. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. 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.

About Bausch + Lomb

Bausch + Lomb is dedicated to protecting and enhancing the gift of sight for millions of people around the world – from the moment of birth through every phase of life. Its comprehensive portfolio of more than 400 products includes contact lenses, lens care products, eye care products, ophthalmic pharmaceuticals, over-the-counter products and ophthalmic surgical devices and instruments. Founded in 1853, Bausch + Lomb has a significant global research and development, manufacturing and commercial footprint with approximately 13,000 employees and a presence in nearly 100 countries. Bausch + Lomb is headquartered in Vaughan, Ontario with corporate offices in Bridgewater, New Jersey. For more information, visit www.bausch.com and connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Instagram](#).

Forward-looking Statements

This news release may contain forward-looking statements, which may generally be identified by the use of the words “anticipates,” “hopes,” “expects,” “intends,” “plans,” “should,” “could,” “would,” “may,” “believes,” “estimates,” “potential,” “target,” or “continue” and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in Bausch + Lomb’s filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch + Lomb, including but not limited to its project development timelines, launches and costs (which may increase). Readers are cautioned not to place undue reliance

on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch + Lomb undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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