

Bausch + Lomb Launches MIEBO™ (Perfluorohexyloctane Ophthalmic Solution) in the United States

MIEBO is the First and Only Prescription Eye Drop that Directly Targets Tear Evaporation, the Leading Cause of Dry Eye Disease

VAUGHAN, Ontario, Sept. 12, 2023 – Bausch + Lomb Corporation (NYSE/TSX: BLCO), a leading global eye health company dedicated to helping people see better to live better, today announced the U.S. commercial launch of MIEBO (perfluorohexyloctane ophthalmic solution) for the treatment of the signs and symptoms of dry eye disease (DED). MIEBO is the first and only prescription eye drop approved for DED that directly targets tear evaporation.

“More and more Americans are suffering from dry eye disease, due in large part to today’s multi-screen lifestyles,” said Andrew Stewart, president, Global Pharmaceuticals and International Consumer, Bausch + Lomb. “With MIEBO, eye care professionals now have a prescription eye drop that directly addresses tear evaporation, the leading cause of dry eye disease.”

DED affects more than 38 million Americans, with approximately nine in 10 experiencing evaporative dry eye.^{1,2} When not addressed, tear evaporation may lead to worsening of the condition by triggering a cycle of inflammation and ocular surface damage.^{3,4} MIEBO is a single ingredient, water-, preservative- and steroid-free prescription eye drop that spreads quickly and comfortably. It is designed to address the signs and symptoms of DED by reducing tear evaporation at the ocular surface.⁵⁻⁷

The U.S. Food and Drug Administration (FDA) [approved](#) MIEBO in May 2023, based on consistent results from two pivotal phase 3 trials. Its clinical development program includes the first and only phase 3 program for any FDA-approved prescription DED product composed entirely of patients with both DED and clinical signs of Meibomian gland dysfunction (MGD). MGD is a major cause of DED development and progression, with approximately 86% of people with DED having excessive tear evaporation associated with MGD.² In the clinical trials, MIEBO delivered significant improvements in the signs and symptoms of DED and consistently met its primary clinical sign and patient-reported symptom endpoint. The most common adverse reactions experienced with MIEBO was blurred vision (1% to 3% of patients reported blurred vision and eye redness).

For more information on MIEBO, visit www.MIEBO.com.

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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.

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

About Dry Eye Disease

DED is a chronic inflammatory ocular surface disease that is commonly characterized by dryness, stinging, burning, grittiness and/or episodes of blurred vision.^{8,9} The two main types of dry eye disease are aqueous deficient and evaporative. Aqueous-deficient dry eye occurs when the eyes do not produce enough tears. Evaporative dry eye is due to a deficient tear film lipid layer. The most common type of dry eye is evaporative.²

About MIEBO Phase 3 Clinical Trials

FDA approval of MIEBO was based on results from two 57-day, multi-center, randomized, double-masked saline-controlled studies, GOBI and MOJAVE. The studies assessed a total of 1,217 patients who received MIEBO or hypotonic saline (0.6%) in a 1:1 ratio.^{10,11}

In these 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 was blurred vision (1% to 3% of patients reported blurred vision and eye redness).

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. 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.

References

1. Downs P. 2020 Dry Eye Products Market Report: A Global Analysis for 2019 to 2025. Market Scope; 2020.
2. Lemp, MA, Crews, LA, Bron AJ. (2012). Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Cohort: a retrospective study. *Cornea*, 31(5), 472-478. 2012;31(5):472-478. doi:10.1097/ICO.0b013e318225415a.
3. Craig JP, Nelson JD, Azar DT, et al. TFOS dews II report executive summary. *Ocul Surf*. 2017;15(4):802-812. doi:10.1016/j.tos.2017.08.003.
4. Baudouin C, Messmer EM, Aragona P, et al. Revisiting the vicious circle of dry eye disease: a focus on the pathophysiology of meibomian gland dysfunction. *Br J Ophthalmol*. 2016;300-203. doi:10.1136/bjophthalmol-2015-307415.
5. Data on file.
6. Nichols KK, Foulks GN, Bron AJ, et al. The international workshop on Meibomian gland dysfunction: executive summary. *Invest Ophthalmol Vis Sci*. 2011;52(4):1922-1929. doi:10.1167/iovs.10-6997a
7. Borchman D, Vittitow J, Ewurum A, Veligandl SR. Spectroscopic study of perfluorohexyloctane human Meibum interactions. *Invest Ophthalmol Vis Sci*. 2022;63:1525.
8. Dana R, Bradley JL, et al. Estimated prevalence and incidence of dry eye disease on coding analysis of a large, all-age United States health care system. *Am J Ophthalmol*. 2019;202:47-54. doi:10.1016/j.ajo.2019.01.026.
9. Dana R, Meunier J, Markowitz Jt, Joseph C, Siffel C. Patient-reported burden of Dry Eye disease in the United States: Results of an online cross-sectional survey. *Am J Ophthalmol*. 2020;216,7-17. doi:10.1016/j.ajo.2020.03.044.
10. Tauber J, Berdy GJ, Wirta DL, et al. NOV03 for dry eye disease associated with meibomian gland dysfunction: Results of the Randomized Phase 3 GOBI Study. *Ophthalmology*. 2023;130(5):516-524. doi:10.1016/j.ophtha.2022.12.021.
11. Sheppard J, Kurata F, Epitropoulos AT, et al. NOV03 for signs and symptoms of dry eye disease associated with meibomian gland dysfunction: The randomized phase 3 Mojave study. *American Journal of Ophthalmology*. 2023;252:265-274. doi:10.1016/j.ajo.2023.03.008.

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