Bausch + Lomb Announces Publication of Phase 4 Data on the Early Effects of MIEBO® (perfluorohexyloctane ophthalmic solution) on Patient-Reported Outcomes in Dry Eye Disease in Ophthalmology and Therapy Journal

VAUGHAN, Ontario, March 20, 2025 – Bausch + Lomb Corporation (NYSE/TSX: BLCO), a leading global eye health company dedicated to helping people see better to live better, today announced *Ophthalmology and Therapy* has published results from a phase 4 study which assessed early patient-reported outcomes with MIEBO in patients with dry eye disease (DED). MIEBO, indicated for the signs and symptoms of DED, is the first and only prescription treatment to directly target tear evaporation These results shed light on the benefits of MIEBO after the first use and during the first two weeks of treatment. These data build on results from the GOBI and MOJAVE pivotal studies in which patients experienced significant improvement in the signs and symptoms of DED as early as day 15, with continued improvement through day 57.*

"We know that the symptoms of dry eye disease, which include eye dryness, blurred vision, burning, stinging and eye pain, can have a significant impact on daily activities such as reading, driving, working on a computer and using devices," said Andrew Stewart, president, Global Pharmaceuticals and International Consumer, Bausch + Lomb. "These study results build on an impressive data set showing MIEBO as a well-tolerated and effective treatment option for dry eye disease that also can deliver much-needed, fast-acting symptom relief. In particular, the study answers the question of how quickly patients can experience relief prior to day 15, which was the first evaluation point in the phase 3 studies."

The prospective, multicenter, open-label phase 4 study evaluated the effect of MIEBO on symptom severity and frequency early in treatment.* Inclusion criteria aligned with the phase 3 studies where all patients had a history of dry eye disease and evidence of meibomian gland dysfunction. Patients completed early outcome surveys during four clinic visits (day 1 [pretreatment; 5 and 60 minutes post-first administration] and days 3, 7, and 14). Patients rated symptom severity, symptom frequency and treatment satisfaction on a visual analog scale (VAS) from 0 to 100.

"Rapid relief of dry eye symptoms is an important factor for adherence to treatment," said Shane R. Kannarr, OD, study author and optometrist at Kannarr Eye Care in Kansas. "These patient-reported results show that MIEBO provided relief from dry eye symptoms quickly – in some cases in as little as five minutes after the patient's first use – and that relief was maintained and improved over the two-week period. The study also demonstrated high patient treatment satisfaction, another important element for patient compliance, and patients described the product as silky, smooth and soothing."

Key points from the trial (for all results $P<0.0001$):

- Patients reported that MIEBO significantly reduced overall symptom severity at the primary endpoint of day 7.
    - The primary endpoint of change from baseline in the severity of overall dry eye symptoms at day 7 was met. Mean overall symptom severity decreased significantly from 72.1 (17.0) at baseline to 27.8 (22.3) at day 7 (mean change, − 44.5).
- Significant symptom relief was observed within 5 and 60 minutes after a single administration on day 1:
    - The mean score on the VAS for overall dry eye symptoms was 72.1 (17.0) at baseline and decreased to 38.5 (22.8) at 5 min post-administration and 31.7 (22.1) at 60 min post-administration.
- Significant reductions were seen for overall symptom severity and across all symptoms, including dryness, blurred vision, eye irritation, light sensitivity, eye tiredness, burning/stinging, itching and eye pain, at all post-baseline assessments.
- Significant decreases were also observed in mean frequency of awareness of dry eye symptoms, fluctuations in quality of vision and time experiencing the most bothersome symptoms:

	Mean Frequency of Awareness of Dry Eye Symptoms	Fluctuations in Quality of Vision	Mean % of Time Experiencing Most Bothersome Symptoms
Baseline	77.6%	62.8%	77.9%
Day 3	39.7%	29.8%	46.7%
Day 7	32.6%	24.5%	41.3%
Day 14	27.6%	19.4%	34.7%

- Median satisfaction ratings increased steadily from 83.0 at day 3, 86.0 at day 7, and 90.0 at day 14, reflecting high patient satisfaction with MIEBO.
- From 10 descriptors, study participants most commonly chose “silky, smooth and soothing” to describe how the drop felt on administration.
- MIEBO was well tolerated with no reports of treatment-related adverse events.

For more information about MIEBO, please visit www.miebo.com.

*About MIEBO Pivotal and Early Efficacy Studies

GOBI and MOJAVE were two pivotal 57-day, multicenter, double-masked, saline-controlled studies conducted in adults ≥18 years old with a self-reported history of DED in both eyes and clinical signs of meibomian gland dysfunction. Patients administered one drop of MIEBO four times daily during the study. Primary endpoints were change from baseline in total corneal staining and change from baseline in eye dryness score (Visual Analog Scale [VAS]) at Day 57. Day 15 was the earliest time point at which signs and symptoms were evaluated in the trials. Day 57 (primary endpoints) was the last.

Individual symptom data for GOBI: Mean (SD) CFB –27.4 (27.9) for MIEBO (n = 289) vs –19.7 (26.7) for control (n = 279) (P<0.001) at Day 57. Individual symptom data for MOJAVE: Mean (SD) CFB –29.5 (28.6) for MIEBO (n = 302) vs –19.0 (27.2) for control (n = 296) (P<0.001) at Day 57.

The Early Efficacy study was a prospective, multicenter, open-label phase 4 study in adults ≥18 years old (N=99) with a self-reported history of DED in both eyes and clinical signs of meibomian gland dysfunction. Patients administered one drop of MIEBO four times daily in both eyes for 14 days. The primary endpoint was change from baseline in the severity of overall dry eye symptoms at day 7 (Visual Analog Scale [VAS]). Study limitations include the open-label design, absence of a control group, lack of assessment of clinical signs of DED, and limited diversity of the study population.

Disclaimer: Data should be interpreted with caution. No formal conclusions should be drawn.

INDICATION
MIEBO® (perfluorohexyloctane ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease.

IMPORTANT SAFETY INFORMATION

- MIEBO should not be administered while wearing contact lenses. Contact lenses should be removed before use and for at least 30 minutes after administration of MIEBO
- Instruct patients to instill one drop of MIEBO into each eye four times daily
- The safety and efficacy in pediatric patients below the age of 18 have not been established
- The most common ocular adverse reaction was blurred vision (1% to 3% of patients reported blurred vision and conjunctival redness)

You 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

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.1,2 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.3

About Bausch + Lomb

Bausch + Lomb is dedicated to protecting and enhancing the gift of sight for millions of people around the world – from birth through every phase of life. Its comprehensive portfolio of approximately 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 13,500 employees and a presence in approximately 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 X, LinkedIn, Facebook and Instagram.

References

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3. 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:10.109/ICO.0b013e318225415a.

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