Bausch + Lomb Announces FDA Approval Of LOTEMAX® SM (loteprednol Etabonate Ophthalmic Gel) 0.38% For The Treatment Of Postoperative Inflammation And Pain Following Ocular Surgery

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LOTEMAX SM Is Formulated with SubMicron Technology for Efficient Penetration To Key Ocular Tissues[1]

BRIDGEWATER, N.J., Feb. 25, 2019 /PRNewswire/ -- Bausch + Lomb, a leading global eye health company and wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TXS: BHC), today announced that the U.S. Food and Drug Administration (FDA) has approved LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%, a new gel formulation for the treatment of postoperative inflammation and pain following ocular surgery.[2] Compared to LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%, LOTEMAX SM delivers a submicron particle size for faster drug dissolution in tears.[3,4] LOTEMAX SM also provides two times greater penetration to the aqueous humor compared to LOTEMAX GEL.[1]

"With the FDA approval of LOTEMAX SM, physicians can now prescribe to their patients our most advanced loteprednol etabonate formulation to date, indicated for the treatment of postoperative inflammation and pain following ocular surgery," said Joe Gordon, U.S. president, Bausch + Lomb. "Since Bausch + Lomb introduced the first formulation of loteprednol etabonate more than 20 years ago, we have continued to advance formulations that meet the changing needs of our patients. We are planning to make LOTEMAX SM available as a new treatment option for patients by April 2019."

Based on Bausch + Lomb's history and experience in loteprednol etabonate innovation over the last two decades, the Company developed LOTEMAX SM, which uses SubMicron (SM) Technology to adhere to the ocular surface and then penetrate key ocular tissues.[1,6] The submicron particles in LOTEMAX SM help improve drug exposure into the aqueous humor.[1] Similar to LOTEMAX GEL, LOTEMAX SM was formulated with moisturizing ingredients (glycerin and propylene glycol),[6] a pH close to that of human tears[7] and the lowest preservative percentage in a loteprednol etabonate formulation.[2,5,8-12]

"Patients undergoing ocular surgery, including cataract surgery, often experience inflammation that needs to be treated. This inflammation can be painful and result in serious complications," said Marguerite McDonald, M.D., F.A.C.S., ophthalmologist and clinical professor of ophthalmology, New York University (NYU) School of Medicine. "In two clinical trials, LOTEMAX SM was significantly more effective than vehicle in completely resolving ocular inflammation and pain following cataract surgery, one of the most common operations performed in the United States. LOTEMAX SM provides proven efficacy, efficient penetration, and less frequent dosing compared to LOTEMAX GEL, and the tolerability profile that we have come to expect from the loteprednol etabonate molecule. Together these factors support LOTEMAX SM as an important new option for many of my patients who require treatment for inflammation and pain following ocular surgery."

LOTEMAX SM Clinical Data
The FDA approval of LOTEMAX SM was based on data from two randomized, multicenter, double-masked, parallel-group, vehicle-controlled studies in 742 patients with postoperative inflammation following cataract surgery.[2] LOTEMAX SM was administered three times daily to the affected eye beginning the day after surgery and was shown to be significantly more effective than vehicle in completely resolving ocular inflammation and pain following cataract surgery.[2] In these two studies, twice as many patients treated with LOTEMAX SM achieved complete inflammation resolution at day eight compared to vehicle (30 percent vs. 15 percent, $p<0.0001$).[2] Additionally, significantly more patients treated with LOTEMAX SM were pain-free compared to vehicle at day eight (74 percent vs. 49 percent, $p<0.0001$) and day three (secondary endpoint; 72 percent vs. 50 percent, $p<0.0001$).[2,13]

In the studies, LOTEMAX SM had a proven safety profile. There were no treatment-emergent adverse drug reactions that occurred in more than one percent of the subjects in the three times daily group compared to vehicle.

INDICATION
LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

IMPORTANT SAFETY INFORMATION

- LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If LOTEMAX® SM is used for 10 days or longer, IOP should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.
- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those with diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infections.
- Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
- Contact lenses should not be worn when the eyes are inflamed.
- There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

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 Prescribing Information for LOTEMAX® SM.

About Bausch + Lomb
Bausch + Lomb, a Bausch Health Companies Inc. company, is a leading global eye health organization that is solely focused on helping people see. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in more than 100 countries. For more information, visit www.bausch.com.

About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at www.bauschhealth.com.

Forward-looking Statements
This news release may contain forward-looking statements which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "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, risks and uncertainties discussed in Bausch Health's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the 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 Health 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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