BAUSCH Health

Bausch + Lomb Announces The U.S. Launch Of LOTEMAX® SM (Loteprednol Etabonate Ophthalmic Gel) 0.38% For The Treatment Of Postoperative Inflammation And Pain Following Ocular Surgery

April 02, 2019

Shipments to U.S. Pharmaceutical Distributors Begin

BRIDGEWATER, N.J., April 2, 2019 /PRNewswire/ -- Bausch + Lomb, a leading global eye health company and wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TXS: BHC), today announced it has begun distributing LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% to U.S. pharmaceutical distributors. The company received final approval by the U.S. Food and Drug Administration (FDA) on Feb. 22, 2019. LOTEMAX SM is a new gel drop formulation of loteprednol etabonate, which was designed with novel SubMicron (SM) technology for efficient penetration to key ocular tissues[1,2] at a low preservative (BAK) level[3,5-10] and a pH close to human tears.[4] It is indicated for the treatment of postoperative inflammation and pain following ocular surgery.[3]

"LOTEMAX SM is the culmination of our clinical experience with the loteprednol etabonate compound for more than two decades. We are extremely proud to make this new treatment option available, our most advanced loteprednol etabonate formulation to date, to help our customers address the needs of their patients undergoing ocular surgery who experience postoperative inflammation and pain," said Joe Gordon, U.S. president, Bausch + Lomb.

LOTEMAX SM delivers a submicron particle size and provides two times greater penetration to the aqueous humor as compared to LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%.[2] In addition, LOTEMAX SM was formulated with:

- moisturizing ingredients[1]
- a pH close to that of human tears[4]
- the lowest BAK preservative percentage in a loteprednol etabonate formulation (same percentage as LOTEMAX GEL [0.003 percent])[3,5-10]

"I am excited to now offer my postoperative patients who experience pain and inflammation LOTEMAX SM, with its proven efficacy, efficient penetration, and less frequent dosing compared to LOTEMAX GEL," said Marguerite McDonald, M.D., F.A.C.S., ophthalmologist and clinical professor of ophthalmology, New York University (NYU) School of Medicine. "In addition to the improved dosing compared to LOTEMAX GEL and the established efficacy, LOTEMAX SM offers a tolerability profile that I have come to rely on from the loteprednol etabonate molecule."

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.

DOSAGE AND ADMINISTRATION
Invert closed bottle and shake once to fill tip before instilling drops. Apply one drop of LOTEMAX®

SM into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first two weeks of the post-operative period.

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

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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
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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 Bausch Health'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.

References

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Investor/Media
Contact:
Arthur
Shannon
arthur.shannon@bauschhealth.com

(514) 856-3855
(877) 281-6642 (toll free)

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SOURCE Bausch Health Companies Inc.

877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692

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