

# New Scientific And Clinical Analyses Regarding Bausch + Lomb Surgical And Pharmaceutical Products To Be Presented During The Association For Research In Vision And Ophthalmology Meeting

April 26, 2019

## **Data from the Company's Antibiotic Resistance Monitoring in Ocular Microorganisms (ARMOR) Study will also be Featured**

BRIDGEWATER, N.J., April 26, 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 researchers will present the results of nine new scientific and clinical analyses involving the company's Pharmaceutical and Surgical products, as well as data from the company's Antibiotic Resistance Monitoring in Ocular Microorganisms (ARMOR) surveillance study, during the Association for Research in Vision and Ophthalmology (ARVO) meeting in Vancouver, British Columbia (Apr. 28 - May 2, 2019).

"Bausch + Lomb is deeply committed to supporting continued research on our product portfolio in order to provide practitioners with new information that can help inform their treatment decisions," said Joe Gordon, U.S. president, Bausch + Lomb. "Doing so is part of our commitment to better address the needs of their patients for today and tomorrow."

The scientific posters will feature integrated data from three Phase 3 multicenter, randomized, double-masked clinical trials on the proportion of subjects achieving zero-trace anterior chamber inflammation with the company's new submicron loteprednol formulation, LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%, following cataract surgery, as well as pooled data from three multicenter, randomized clinical studies analyzing the incidence of polybacterial infections in bacterial conjunctivitis and outcomes using besifloxacin ophthalmic suspension 0.6%. Other poster presentations will include an assessment utilizing the eyeTELLIGENCE™ platform on the Stellaris Elite™ vision enhancement system to measure the relative effect of gauge size and surgeon efficiency during vitrectomy surgeries, as well as research regarding future intraocular lens (IOL) designs, next-generation delivery systems and product enhancements.

The ARMOR study analyses will include a ten-year trend analysis, examining antibiotic resistance trends among staphylococcal isolates collected in the ARMOR study to date, as well as a preliminary analysis of the 2018 ARMOR results. Initiated in 2009, the ARMOR surveillance study is the only ongoing multicenter survey of antibiotic resistance patterns specific to ocular pathogens in the United States that allows eye care professionals to track in vitro susceptibility rates for commonly used antibiotics.

The complete schedule (by date) for all poster presentations is as follows:

### Sunday, April 28

- Abstract Number: B0364, Blondeau, J.M. et al. *"Incidence of Polybacterial Infections in Three Bacterial Conjunctivitis Studies and Outcomes with Besifloxacin Ophthalmic Suspension 0.6%."* Sunday, April 28 from 8:00 – 9:45 a.m.
- Abstract Number: B0365, Sanfilippo, C et al. *"Antibiotic Resistance Among Ocular Pathogens – An Update from the 2018 ARMOR Study."* Sunday, April 28 from 8:00 – 9:45 a.m.
- Abstract Number: B0370, Martel, J et al. *"Proportion of subjects achieving zero-trace anterior chamber inflammation with loteprednol etabonate (submicron) gel 0.38% following cataract surgery: Integrated analysis of 3 pivotal trials."* Sunday, April 28 from 8:00 – 9:45 a.m.
- Abstract Number: B0331, Asbell, P et al. *"Longitudinal Trends in Antibiotic Resistance Among Staphylococci Collected in the ARMOR Study."* Sunday, April 28 from 1:00 – 2:45 p.m.
- Abstract Number: A0462, Lau, G et al. *"Comparison of Delivery Forces and Wound Dimensions of New Smaller Incision Injector for Plate-Haptic Intraocular Lens."* Sunday, April 28 from 1:00 – 2:45 p.m.

### Tuesday, April 30

- Abstract Number: B0233, Guenther, G et al. *"Evaluation of the Posterior Optic Square Edge Profile of Hydrophilic Acrylic Intraocular Lenses after Tumble Polishing with a Protective Mask."* Tuesday, April 30 from 11:45 – 1:30 p.m.
- Abstract Number: B0237, Cook, M et al. *"Ex vivo Optical Performance of Two Distinct Aberration-Neutral Monofocal IOL Designs."* Tuesday, April 30 from 11:45 – 1:30 p.m.
- Abstract Number: B0245, Pilon, A et al. *"Comparative Assessment of Outward Radial Forces Exerted by Hydrophobic Acrylic Intraocular Lenses and Capsular Tension Rings Under Common Degrees of Compression."* Tuesday, April 30 from 11:45 – 1:30 p.m.

### Thursday, May 2

- Abstract Number: B0247, Karthik, N et al. *"Evaluating Ophthalmic Surgical Efficiency through the Stellaris® Platform: The Impact of Surgeon Volume and Gauge Size on Pars Plana Vitrectomy."* Thursday, May 2 from 8:00 – 9:45 a.m.

## **Important Safety Information about LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%**

### **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. Steroids should be used with caution in the presence of glaucoma. 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Click  
here**

**for Prescribing Information for LOTEMAX<sup>®</sup> SM.**

### **Important Safety Information about BESIVANCE<sup>®</sup> (besifloxacin ophthalmic suspension) 0.6%**

#### **Indication**

BESIVANCE<sup>®</sup> (besifloxacin ophthalmic suspension) 0.6% is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: *Aerococcus viridans*\*, CDC coryneform group G, *Corynebacterium pseudodiphtheriticum*\*, *Corynebacterium striatum*\*, *Haemophilus influenzae*, *Moraxella catarrhalis*\*, *Moraxella lacunata*\*, *Pseudomonas aeruginosa*\*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis*\*, *Staphylococcus lugdunensis*\*, *Staphylococcus warneri*\*, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius*\*

\*Efficacy for this organism was studied in fewer than 10 infections.

#### **Important Safety Information**

- BESIVANCE<sup>®</sup> is not for injection into the eye.
- As with other anti-infectives, prolonged use of BESIVANCE<sup>®</sup> may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.
- Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with BESIVANCE<sup>®</sup>.
- The most common adverse event reported in approximately 2% of patients treated with BESIVANCE<sup>®</sup> was conjunctival redness. Other adverse events reported in patients receiving BESIVANCE<sup>®</sup> occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.
- Safety and effectiveness in infants below one year of age have not been established.

**Click  
here**

**for full Prescribing Information for BESIVANCE<sup>®</sup>.**

#### **About Bausch + Lomb**

Bausch + Lomb, a division of Bausch Health, 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](http://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](http://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 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.

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### **Investor/Media Contact:**

Arthur

Shannon

[arthur.shannon@bauschhealth.com](mailto:arthur.shannon@bauschhealth.com)

(514) 856-3855

(877) 281-6642 (toll free)

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### Investor Inquiries

[ir@bauschhealth.com](mailto:ir@bauschhealth.com)

877-281-6642

514-856-3855 (Canada)

### Media inquiries

[Corporate.communications@bauschhealth.com](mailto:Corporate.communications@bauschhealth.com)

908-569-3692

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