Bausch + Lomb Will Present New Scientific Data And Analyses On Products And Pipeline Programs During The Association For Research In Vision And Ophthalmology Meeting

April 29, 2021

One Podium Presentation and 11 Poster Presentations to be Featured

LAVAL, QC, April 29, 2021 /PRNewswire/ -- Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), today announced the presentation of new scientific data and clinical analyses, including one podium presentation and 11 poster presentations, during the virtual Association for Research in Vision and Ophthalmology (ARVO) annual meeting, which will take place from May 1-7, 2021. The virtual presentations will feature several of the company's prominent products from its pharmaceutical, surgical and vision care portfolios, as well as data from the company's ongoing Antibiotic Resistance Monitoring in Ocular micRoorganisms (ARMOR) surveillance study. Analyses on the company's investigational drug XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) will also be highlighted.[1]

"The new data and analyses we are presenting at ARVO this year represent our ongoing commitment to research and development across our business and to providing practitioners with new information that can help inform the treatment and care of their patients," said Joe Gordon, U.S. president, Bausch + Lomb. "Among the data to be featured are insights from our ARMOR surveillance study, which continues to be the only ongoing multicenter study in the United States that monitors in vitro antibiotic resistance among ocular pathogens, and data on XIPERE™. We are proud to support these important studies and share the latest findings with eye care professionals during the ARVO meeting."

The ARMOR study analyses will be featured in both a podium presentation, examining the antibiotic resistance trends among staphylococcal isolates collected in the ARMOR study since 2009, and a poster presentation outlining the preliminary analysis of the 2020 ARMOR results. The ARMOR study findings allow eye care professionals to track in vitro susceptibility rates for commonly used antibiotics.

Another poster from the company's vision care portfolio will evaluate the osmoprotective effects of the Bausch + Lomb INFUSE™ silicone hydrogel (SiHy) daily disposable contact lenses packaging lens solution, kalifilcon A(KA), as compared to six other SiHy daily disposable packaging solutions. Bausch + Lomb INFUSE lenses received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in August 2020.

From the company's surgical portfolio, one poster will evaluate the increased hydroxyl radical scavenging activity of ClearVisc™ dispersive ophthalmic viscosurgical device (OVD) and a cohesive OVD. Bausch + Lomb announced the FDA approval of ClearVisc in April. A second poster will analyze the acoustic pressure of 23-, 25- and 27-gauge vitrectomy needles to measure the power, energy-tissue interaction and safety of Vitesse™ ultrasonic device, and another poster will

compare the optical performance of intraocular lenses (IOLs) with three optical designs using an optical raytracing simulation method.

Four other posters will feature new data from the Bausch + Lomb pharmaceuticals portfolio. The first will feature findings from the company's pharmacovigilance database of the occurrence of steroid-associated adverse events related to LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% and all other LOTEMAX® formulations. Another will evaluate the differences in dose uniformity between LOTEMAX® SM and another corticosteroid suspension product when shaken or not shaken.

The last two pharmaceutical posters will feature data on blepharitis, which is an inflammation of the eyelids that makes them red, irritated and itchy with dandruff-like scales that form on the eyelashes. One will evaluate the in vitro activity of tobramycin, the antibacterial in ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension), against common bacterial pathogens associated with the disorder, and the other will compare the in vitro activity of eight antibiotics across six drug classes frequently used to manage blepharitis caused by staphylococci ("staph" bacteria).

The remaining two posters, which will be presented by Clearside Biomedical, Inc., will feature unpublished data on the investigational drug, XIPERE™. The first poster, a post hoc study, will evaluate the safety of suprachoroidal injections (SCIs) utilizing the SCS Microinjector® across multiple clinical trials, and the other poster will analyze the procedural characteristics of SCIs in two non-infectious uveitis trials.

The full schedule of research (by date) to be presented includes:

Sunday, May 2

- "*Monofocal, Diffractive Trifocal and EDOF IOLs*." Xie et al.
- *"New Ophthalmic Viscosurgical Device (OVD) with Enhanced Hydroxyl Radical Scavenging Activity*." Erb et al.

Monday, May 3

- "*Analysis of Longitudinal Antibiotic Susceptibility Trends in Staphylococci: Results from 12 Years of the ARMOR Study*." Asbell et al.
- *"Post hoc Analysis of Clinical Suprachoroidal Injection Experience for Non-infectious Uveitis."* Shah, M.
- *"Safety of Suprachoroidal Injection Procedure Utilizing a Microinjector across Three Retinal Disorders."* Sharma, S.

Tuesday, May 4

- "*In Vitro Potency of Tobramycin Against Common Bacterial Pathogens Implicated in Blepharitis."* Deom et al.

Thursday, May 6

- *"Acoustic power measurements of ultrasonic vitrectomy device and the effects in pig eyes."* Papour et al.

Friday, May 7

- "*Dose uniformity of loteprednol etabonate (submicron) ophthalmic gel 0.38% compared with prednisolone acetate ophthalmic suspension 1.0%."* Marlowe et al.
- "*Occurrence of steroid-associated adverse events with loteprednol etabonate formulations*." Cavet et al.
- "*Interim Analysis of Antibiotic Resistance from Bacterial Pathogens Collected in the 2020 ARMOR Stud*y." Sanfilippo et al.
- "*Comparative In Vitro Activity of Antibiotics Frequently Used in the Management of Staphylococcal Blepharitis*." Kissling et al.

- "*Comparative Analysis of the Osmoprotective Effects of a Novel Contact Lens Packaging Solution on Human Corneal Epithelial Cells*." Byrnes et al.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR CLEARVISC™ OVD

INDICATIONS FOR USE
ClearVisc™ is indicated for use as a surgical aid in ophthalmic anterior segment procedures including: Extraction of a cataract; Implantation of an intraocular lens (IOL)

CONTRAINDICATIONS
There are no contraindications to the use of ClearVisc™ when used as a surgical aid in ophthalmic anterior segment procedures.

PRECAUTIONS
Precautions normally considered during anterior segment procedures are recommended. Pre-existing glaucoma may place patients at risk for increases in intraocular pressure from the OVD during the early postoperative period.

WARNINGS
- Do not use if the sterile barrier has been breached. Sterility cannot be guaranteed, and the patient will be at increased risk for infection.
- An excess quantity of ClearVisc™ should not be used. Excess OVD can cause increased intraocular pressure.
- ClearVisc™ should be removed from the anterior chamber at the end of surgery to prevent or minimize postoperative intraocular pressure increases (spikes). OVD remaining in the eye can cause increased intraocular pressure.
- If the postoperative intraocular pressure increases above expected values, corrective therapy should be administered. Increased intraocular pressure may lead to inflammation or vision loss.
- Do not re-use the cannula. Even after cleaning and rinsing, resterilized cannula could release particulate matter as ClearVisc™ is injected. It is recommended that a single-use disposable cannula be used when administering ClearVisc™. Reuse may cause eye inflammation.
- If any particulate matter is observed, it should be removed by irrigation and/or aspiration. Particulate matter left in the eye may cause increased IOP or Light scattering /obstruction.
- Store at 2° to 8°C (36° to 46°F). Protect from freezing. The shelf life of ClearVisc™ is not guaranteed if it is not properly stored.

ADVERSE REACTIONS
Sodium hyaluronate is a natural component of tissues within the body and is generally well tolerated in human eyes. Transient postoperative inflammatory reactions and increases in intraocular pressure have been reported. Inflammation may result from increased intraocular pressure caused by use of the OVD. Intraocular inflammation, i.e., toxic anterior segment syndrome (TASS), has been attributed to OVDs. Furthermore, vision loss may be possible as a result of increased intraocular pressure and inflammation.

ATTENTION
Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION
Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indication and Important Safety Information about LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%

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
or call 1-800-FDA-1088.

Click
here
for full Prescribing Information for LOTEMAX® SM.

Indication and Important Safety Information about ZYLET (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension)

ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension) is a topical anti-infective and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation.

They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product (tobramycin) is active against the following common bacterial eye pathogens: Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii,* most *Proteus vulgaris strains, Haemophilus influenzae, and H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus and* some *Neisseria species.*

IMPORTANT SAFETY INFORMATION

ZYLET 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 this product is used for 10 days or longer, intraocular pressure 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 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 a 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. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Employment of 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 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.
- Most common adverse reactions reported in patients were injection and superficial punctate keratitis, increased intraocular pressure, burning and stinging upon instillation.

You are encouraged to report 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 ZYLET.

About Bausch + Lomb

Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., 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 approximately 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
www.bauschhealth.com
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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," "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 Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). 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
1. In October 2019, an affiliate of Bausch Health acquired an exclusive license from Clearside Biomedical for the commercialization and development of XIPERE in the United States and Canada.

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