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FOR RELEASE 4/17/2013, Wednesday

Bausch + Lomb Launches PROLENSA™ and Showcases Innovative Additions to its Surgical Product Portfolio at the ASCRS Annual Meeting

U.S. Debut for New Once-Daily PROLENSA™ (bromfenac ophthalmic solution) 0.07 percent
Special Cataract and Refractive Surgical Suites on Display, with Featured
Demonstrations of the VICTUS™ Femtosecond Laser Platform

ROCHESTER, NY — Bausch + Lomb, the global eye health company, will debut *PROLENSA*™ (bromfenac ophthalmic solution) 0.07 percent, its newly approved nonsteroidal anti-inflammatory ophthalmic solution, and highlight innovative additions to its comprehensive line of ophthalmic surgical instruments and therapeutics at its booth (#1926) during the upcoming Annual American Society of Cataract and Refractive Surgery (ASCRS) Symposium (San Francisco, Calif., April 19-23). Attendees will also be able to participate in surgical equipment demonstrations, attend scientific symposia, a CME event and booth talks, and see two dozen scientific podium presentations and posters related to Bausch + Lomb's ophthalmic pharmaceutical and surgical offerings.

New Products and Solutions – The More You Look, The More You See

Among its wide range of pharmaceutical and surgical solutions, Bausch + Lomb will debut the recently approved *PROLENSA* (bromfenac ophthalmic solution) 0.07 percent prescription eye drop, a new once-daily nonsteroidal anti-inflammatory drug (NSAID) for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. *PROLENSA* is an advanced formulation of *Bromday*® (bromfenac ophthalmic solution) 0.09 percent that provides powerful and rapid resolution of inflammation and pain from cataract surgery by leveraging the unique potency of the bromfenac molecule and effective ocular penetration. The advanced formulation allows for a lower concentration of the active ingredient, bromfenac, while maintaining the convenience of once daily dosing. *PROLENSA* will be available in 1.6ml and 3ml bottle sizes.

The company also will highlight *LOTEMAX*® (loteprednol etabonate ophthalmic gel) 0.5 percent gel drop formulation, a new topical corticosteroid formulation in its line of loteprednol etabonate C-20 ester corticosteroid-based ophthalmic products. Introduced in January, *LOTEMAX* Gel is indicated for the treatment of post-operative inflammation and pain following ocular surgery. The unique *LOTEMAX* Gel drop formulation is engineered to adhere to the ocular surface through its mucoadhesive technology. *LOTEMAX* Gel also provides dose uniformity, ensuring that a consistent concentration of loteprednol is delivered in every drop, with no shaking to resuspend the drug required.

Bausch + Lomb will offer demonstrations of its cutting edge surgical platform, the *VICTUS*™ femtosecond laser platform, by appointment, which can be scheduled at the Bausch + Lomb booth (#1926). And, with the recent announcement of a global distribution agreement with Leica Microsystems, the Bausch + Lomb booth will feature several Leica Microsystems ophthalmic microscopes.

The company will also showcase the latest additions to its Bausch + Lomb Storz® industry-leading ophthalmic instrument portfolio for refractive, cataract and vitreo-retinal surgery. This will include a specialized set of instruments designed specifically to complement femtosecond laser procedures and a set of instrumentation for the new Descemet's Membrane Endothelial Keratoplasty procedure developed by Thomas John, M.D., in Chicago, Ill. The instruments will be available for purchase at the Bausch + Lomb booth (#1926).

Scientific Symposia

Bausch + Lomb is sponsoring three scientific symposia including the following:

• "A New Advancement in the Ocular Delivery of Loteprednol Etabonate," on Saturday, April 20 from 7 – 9 p.m. PDT at the InterContinental Hotel's Grand Ballroom.
• "Hot Topics in Cataract Surgery: Femtosecond & IOL Controversies," on Sunday, April 21 from 5 – 6:30 p.m. PDT at the InterContinental Hotel's Grand Ballroom.
• "Selecting an NSAID for Surgery: What Really Matters?," on Sunday, April 19 from 7:30 – 9:30 p.m. PDT at the InterContinental Hotel's Grand Ballroom.

Booth Talks

Bausch + Lomb will host a series of interactive programs in its booth covering the future of cataract surgery, product innovation and practice management. These talks will be led by an impressive and diverse group of highly regarded speakers, including Drs. Rob Weinstock, John Sheppard, Mark Packer and Jeff Whitman. The talks begin on Saturday, April 20 and continue through Monday, April 22. A full schedule will be available at the Bausch + Lomb booth (#1926). In addition, the company's chief medical officer, Cal Roberts, M.D., and other members of the Global Medical Affairs team will be on hand to engage the ophthalmic community and answer questions.

CME Events

Bausch + Lomb is supporting, "Knocking Down Inflammatory Barriers to Success in Refractive Cataract Surgery," a CME event featuring moderator Terry Kim, M.D.; and faculty, David F. Chang, M.D.; Uday Devgan, M.D.; Francis S. Mah, M.D.; and Keith Warren, M.D. The event is scheduled to take place on Saturday, April 20 from 5:30 – 6:30 p.m., with registration opening at 5 p.m.

Scientific Podium Presentations and Posters

Bausch + Lomb will present 23 podium presentations and e-posters, including several on the new *enVista*® hydrophobic acrylic intraocular lens, the first and only IOL approved in the U.S. with labeling that states: "No glistenings of any grade were reported for any subject at any visit in the clinical study".[1,2]

The schedule for all Bausch + Lomb podium presentations and posters is as follows:

Saturday:

Endl MJ, et al. "Assessment of Corneal Flap Thickness Precision with New Femtosecond Laser." [ASCRS Posters P2: Keratorefractive: KIOSKS (Moscone) Saturday, April 20, 8 a.m. – 5 p.m. PDT]

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Majmudar P, et al. “Safety of Besifloxacin Ophthalmic Suspension 0.6 percent in Cataract Surgery Patients: Prospective Surveillance Study.” [ASCRS Posters P1: Intraocular Surgery (Cataract and Refractive): KIOSKS (Moscone) Saturday, April 20 8 a.m. – 5 p.m. PDT]
Rajpal R, et al. “Resolution of Anterior Chamber Cells and Flare with Loteprednol Etabonate 0.5 percent Gel: New Treatment for Post-Cataract Inflammation and Pain.” [ASCRS Posters P1: Intraocular Surgery (Cataract and Refractive): KIOSKS (Moscone) Saturday, April 20 8 a.m. – 5 p.m. PDT]
Stephenson P, et al. “Clarity of Vision with New Hydrophobic Acrylic IOL.” [ASCRS Posters P1: Intraocular Surgery: KIOSKS (Moscone) Saturday, April 20, 8 a.m. – 5 p.m. PDT]
Stodulka P, et al. “High-Volume Use of Femtosecond Laser-Assisted Cataract Surgery.” [ASCRS Posters P1: Intraocular Surgery: KIOSKS (Moscone) Saturday, April 20, 8 a.m. – 5 p.m. PDT]
Ang RT et al. “Prospective Comparison of 1 Accommodating and 2 Multifocal IOLs: Visual Acuity, Refractive Outcome and Contrast Sensitivity at Year 1.” [ASCRS Paper Session 1-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 121 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]
Chu R, Pepose JS, Qazi MA et al. “Comparison of NEI-RQL-42 and SVI Quality of Life Measures After Bilateral Implantation of 3 FDA-Approved Presbyopia-Correcting IOLs at 6-months.” [ASCRS Paper Session 1-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 121 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]
Dell SJ et al. “Comparison of Free-Floating Capsulotomy - Rate of 2 Femtosecond Laser Systems for Cataract Surgery.” [ASCRS Paper Session 1-B: Intraocular Surgery Femtosecond Laser: Room 130 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]
Stephenson P et al. “Use of Intraoperative Wavefront Aberrometer with New Aspheric Hydrophobic Acrylic IOL.” [ASCRS Paper Session 1-D: Intraocular Surgery Power Calculations: Room 123 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]
Chee S, Ti S et al. “Early Visual Outcomes of First 100 Cases of Femtosecond Laser-Assisted Cataract Surgery at Ophthalmic Institution in Singapore.” [ASCRS Paper Session 1- G: Intraocular Surgery Femtosecond laser: Room 120 (Moscone), Saturday, April 20, 3 – 4:45 p.m. PDT]
Daya SM, Nanavaty MA, Espinosa M et al. “Ultrasound Power, Translenticular Hydrodissection and Lens Fragmentation in Femtosecond laser Cataract Surgery.” [ASCRS Paper Session 1-G: Intraocular Surgery Femtosecond laser: Room 120 (Moscone), Saturday, April 20, 3 – 4:45 p.m. PDT]
Pepose JS, Qazi MA et al. “Prospective Randomized Evaluation of Bilateral Implantation of 3 FDA-Approved Presbyopia-Correcting IOLs at 6-months.” [ASCRS Paper Session 1-I: Intraocular Surgery Presbyopia-Correcting IOLs: Room 130 (Moscone), Saturday, April 20, 3– 4:30 p.m. PDT]
Qazi MA, Chu R, Pepose JS et al. “Evaluation of Visual Metrics Using OQAS After Bilateral Implantation of Accommodating or Multifocal IOLs.” [ASCRS Paper Session 1-I: Intraocular Surgery Presbyopia-Correcting IOLs: Room 130 (Moscone), Saturday, April 20, 3 – 4:30 p.m. PDT]
Sunday:
Kandavel R, Colvard M et al. “Seven-Year Visual Acuity Outcomes with an Accommodating IOL.” [ASCRS Paper Session 2-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 123 (Moscone), Sunday, April 21, 8– 9:30 a.m. PDT]
Page TP et al. “Management of Post-occlusion Surge with Advanced Fluidics.” [ASCRS Paper Session 2-E: Intraocular Surgery Phaco Technology: Room 125 (Moscone), Sunday, April 21, 8– 9:30 a.m. PDT]
Schechter B et al. “Improved Surgical Efficiency with Newer Model Phacoemulsification System.” [ASCRS Paper Session 2-E: Intraocular Surgery Phaco Technology: Room 125 (Moscone), Sunday, April 21, 8 – 9:30 a.m. PDT]
Roberts, C, Stodulka. P. “Improved Surgical Productivity With Incorporation of Femtosecond Laser in Cataract Surgery.” [ASCRS Paper Session 2-A: Intraocular Surgery Femtosecond Laser: Room 120 (Moscone) 8 - 9:30 a.m. PDT]
Whitman J et al. “Anterior Capsulotomy Diameter Accuracy and Refractive Outcomes using Femtosecond Laser.” [ASCRS Paper Session 2-A: Intraocular Surgery Femtosecond Laser: Room 120 (Moscone), Sunday, April 21, 8– 9:30 a.m. PDT]
Haq F, Whitman J et al. “Corneal Flap Creation with New Femtosecond Laser used During LASIK.” [ASCRS Paper Session 2-J: Intraocular Surgery Keratorefractive LASIK: Room 123 (Moscone), Sunday, April 21, 1 – 2:30 p.m. PDT]
Wallace R et al. “Burst Hemiflip Approach to Phacoemulsification: Effect of Stable Chamber Fluidics on Nuclear Disassembly and Removal.” [ASCRS Paper Session 2-O: Intraocular Surgery Phaco: Room 121 (Moscone), Sunday, April 21, 3– 4:30 p.m. PDT]
Monday:
Guedj M, Monnet D et al. “Prospective Evaluation of New Hydrophobic Toric IOL.” [ASCRS Paper Session 4-C: Intraocular Surgery Toric IOLs: Room 125 (Moscone), Monday, April 22, 8 – 9:30 a.m. PDT]
Malyugin BE, Golovin AV et al. “Clinical Outcomes with New Hydrophobic Acrylic IOL.” [ASCRS Paper Session 4-F: Russian Papers: Room 125 (Moscone), Monday, April 22, 8– 9:45 a.m. PDT]
Nichamin LD et al. “Rotational Stability of New Foldable One-Piece Hydrophobic Acrylic IOL.” [ASCRS Paper Session 4-B: Intraocular Surgery Monofocal IOLs: Room 121 (Moscone), Monday, April 22, 8 – 9:30 a.m. PDT]
Packer M et al. “Implantation of Glistening-Free One-Piece Hydrophobic Acrylic IOL in Cataract patients: Safety and Visual Outcomes.” [ASCRS Paper Session 4-H: Intraocular Surgery Monofocal IOLs: Room 123 (Moscone), Monday, April 22, 10 – 11:30 a.m. PDT]

About PROLENSA

PROLENSA™ (bromfenac ophthalmic solution) 0.07 percent is a once-daily, topical nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. *PROLENSA* is an advanced formulation of *BROMDAY*® (bromfenac ophthalmic solution) 0.09 percent that provides proven once-daily efficacy with a lower concentration of bromfenac.

Dosage and Administration

Instill one drop into the affected eye once daily beginning one day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Important Risk Information about *PROLENSA* (bromfenac ophthalmic solution) 0.07 percent.

Warnings and Precautions

Sulfite allergic reactions

Slow or delayed healing

Potential for cross-sensitivity

Increased bleeding of ocular tissues

Corneal effects, including keratitis

Contact lens wear

Adverse Reactions

The most commonly reported adverse reactions in three – eight percent of patients were, anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

Please see full prescribing information(53.5 KB, PDF) for *PROLENSA*.

About LOTEMAX GEL

LOTEMAX® GEL is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular

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agent by the FDA in 1998 as *LOTEMAX* (lotepredenol etabonate ophthalmic suspension) 0.5 percent, indicated for the treatment of steroid-responsive 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, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation. *LOTEMAX* Ointment (loteprednol etabonate ophthalmic ointment) 0.5 percent is also available 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 or two drops of *LOTEMAX* GEL into the affected eye(s) four times daily after surgery and continuing throughout the first two weeks of the post-operative period.

Dosage Forms and Strengths

Topical ophthalmic gel: loteprednol etabonate ophthalmic gel 0.5 percent.

Important Risk Information about LOTEMAX GEL

Contraindications:

LOTEMAX GEL 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.

Warnings and Precautions

Intraocular pressure (IOP) increase - Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.

Cataracts - Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed healing - Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation and occurrence of perforations in those with diseases causing corneal and scleral thinning. 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.

Bacterial infections - Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infection. In acute purulent conditions, steroids may mask infection or enhance existing infections.

Viral infections – Use 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 - 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.

Contact lens wear - Patients should not wear contact lenses when using *LOTEMAX* GEL.

Adverse Reactions

The most common ocular adverse drug reactions were anterior chamber inflammation (five percent), eye pain (two percent) and foreign body sensation (two percent).

Please see full prescribing information(155.2 KB, PDF) for *LOTEMAX* Gel.

About BESIVANCE

Besivance® (besifloxacin ophthalmic suspension) 0.6 percent, 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.

Dosage and Administration

Instill one drop in the affected eye(s) three times a day, four to twelve hours apart for seven days. (2)

Dosage Forms and Strengths

7.5 mL size bottle filled with five mL of besifloxacin ophthalmic suspension, 0.6 percent (3)

Important Risk Information about BESIVANCE

Contraindications:

None

Warnings and Precautions

Topical Ophthalmic Use Only.

Growth of resistant organisms with prolonged use.

Avoidance of contact lenses. Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with *Besivance* (besifloxacin ophthalmic suspension) 0.6 percent.

Adverse Reactions

The most common adverse reaction reported in two percent of patients treated with *Besivance* was conjunctival redness.

Please see full prescribing information(214.8 KB, PDF) for *Besivance*.

About Bausch + Lomb

Bausch + Lomb is a leading global eye health company that is solely focused on protecting, enhancing, and restoring people's eyesight. Our core businesses include ophthalmic pharmaceuticals, contact lenses and lens care products, and ophthalmic surgical devices and instruments. We globally develop, manufacture and market one of the most comprehensive product portfolios in our industry, which are available in more than 100 countries. Founded in 1853, our company is headquartered in Rochester, NY, and employs more than 11,000 people worldwide.

REFERENCES

1. Bausch & Lomb Incorporated. Data on file, 2009.
2. Tetz. ASCRS. 2009.

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