Bausch + Lomb Announces Publication Of Pivotal Phase 3 Data On Loteprednol Etabonate Ophthalmic Gel, 0.38% In Journal Of Cataract And Refractive Surgery

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Formulation Significantly More Effective than Vehicle in Resolving Ocular Inflammation and Pain Following Cataract Surgery

LAVAL, Quebec, Sept. 5, 2018 /PRNewswire/ -- Bausch + Lomb, a leading global eye health company and wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced that the *Journal of Cataract and Refractive Surgery (JCRS*) has published results of a pivotal Phase 3, multicenter, double-masked, vehicle-controlled, randomized, parallel-group study that evaluated the clinical safety and efficacy of submicron loteprednol etabonate ophthalmic gel, 0.38%.[1]

In the study, this investigational formulation of loteprednol etabonate met both of the primary efficacy endpoints in that it was significantly more effective than vehicle in completely resolving ocular inflammation and pain following cataract surgery. Additionally, the results showed that submicron loteprednol etabonate ophthalmic gel, 0.38% had an acceptable safety profile regardless of whether it was administered two or three times per day.

Submicron loteprednol etabonate ophthalmic gel, 0.38% has a reduced concentration and reduced dosing frequency versus existing formulations of loteprednol etabonate.

"Patients who undergo cataract surgery commonly experience inflammation that can result in pain, compromised vision, increased intraocular pressure, and other complications when untreated," said Raymond Fong, M.D., founder of Raymond Fong Eye Care in New York, and lead author of the publication. "Although topical corticosteroids are widely used to reduce postoperative inflammation and pain, they are associated with potential side effects. These results are very encouraging as they show the efficacy of the submicron loteprednol etabonate ophthalmic gel, 0.38% in eliminating ocular inflammation and pain after cataract surgery with a safety profile similar to other loteprednol etabonate formulations."

The published Phase 3 study, which enrolled 514 patients, showed that a significantly greater proportion of patients who received submicron loteprednol etabonate ophthalmic gel, 0.38% dosed twice daily or three times daily had complete resolution of anterior chamber cells on postoperative day 8 (26.9 percent and 28.7 percent, respectively) compared with the vehicle group (9.3 percent; $p<0.0001$). Similarly, a significantly greater proportion of patients who received submicron loteprednol etabonate ophthalmic gel, 0.38% twice daily or three times daily had no ocular pain (grade 0) on day 8 (73.7 percent and 73.1 percent, respectively) compared with the vehicle group (47.7 percent; $p<0.001$). For patients in the submicron loteprednol etabonate ophthalmic gel, 0.38% group, statistically significant differences in both anterior chamber cells and ocular pain were sustained at all subsequent visits (through postoperative day 18) relative to vehicle. Additionally, significantly fewer patients in the submicron loteprednol etabonate ophthalmic gel, 0.38% twice daily group and three times daily group (14.0 percent and 11.1 percent, respectively) required rescue medication by day 8 compared with those in the vehicle group (41.9 percent; $p<0.0001$). The most common ocular adverse events were eye pain, photophobia (extreme sensitivity to light), and foreign body sensation.

"Bausch + Lomb is committed to innovation and addressing unmet needs in eye care. This submicron loteprednol etabonate ophthalmic gel, 0.38% is an example of continued advancements in our portfolio," said Tracy Valorie, general manager and senior vice president, U.S. Pharmaceuticals and Surgical, Bausch + Lomb. "The results highlighted in this publication support this promising investigational ophthalmic gel as a potential new treatment for postoperative inflammation and pain following ocular surgery, and we look forward to bringing it to market as quickly as possible."

The U.S. Food and Drug Administration has accepted the New Drug Application for submicron loteprednol etabonate ophthalmic gel, 0.38% with a Prescription Drug User Fee Act (PDUFA) action date of Feb. 25, 2019.

About the Phase 3 Study
The Phase 3 study was conducted at 45 ophthalmology practices in the United States and enrolled 514 patients age 18 years or older who had anterior chamber cells grade 2 or higher (6 to 15 cells) the day after uncomplicated cataract surgery. Study participants were randomized to one of four treatment groups (submicron loteprednol etabonate ophthalmic gel, 0.38% twice daily, submicron loteprednol etabonate ophthalmic gel, 0.38% three times daily, vehicle gel twice daily, or vehicle gel three times daily) for 14 days. The primary efficacy endpoints were the proportion of patients with complete resolution of anterior chamber cells (defined as a grade of 0 [or no cells]), a marker of ocular inflammation, and the proportion of patients with grade 0 pain (no pain) at postoperative day 8 in the submicron loteprednol etabonate ophthalmic gel, 0.38% twice daily, submicron loteprednol etabonate ophthalmic gel, 0.38% three times daily, and the combined vehicle groups. Safety and tolerability endpoints included ocular symptoms other than pain (e.g., itching, tearing, and discharge), study drug sensation, the incidence of ocular and non-ocular adverse events, and ocular signs (biomicroscopy), among others. Study participants who experienced worsening or no change in inflammation could be placed on anti-inflammatory rescue medication at any time during the trial.

About Cataracts and Cataract Surgery
A cataract is a clouding of the lens in the eye, caused by the clumping of protein, that affects vision.[2] People with cataracts can experience cloudy or blurry vision, poor night vision, double vision or multiple images in one eye.[2] Most cataracts are related to aging; by age 80, more than half of all Americans either have a cataract or have had cataract surgery.[2] Other risk factors include diabetes, steroid use, smoking, alcohol use, and prolonged exposure to ultraviolet sunlight.[2]

Surgery is the only effective treatment for cataracts. It involves removing the cloudy lens and replacing it with an artificial lens.[2] Cataract removal is one of the most common operations performed in the United States[2] and is the most commonly performed surgical procedure in the United States Medicare population.[3] Both the annual total volume and age-adjusted rates of cataract surgery have increased substantially over the last four decades – from an estimated rate of 13.4 per 1,000 Medicare beneficiaries in 1980, to 76.9 per 1,000 in 2014.[3,4] The rate is significantly higher for females vs. males and for those age 75 to 84 versus those older.[3] Cataract surgery is highly effective, with approximately 90 percent of people experiencing better vision following cataract surgery.[2]

About Loteprednol Etabonate Ophthalmic Gel, 0.38%
Submicron loteprednol etabonate ophthalmic gel, 0.38% is an investigational gel formulation of loteprednol etabonate that utilizes a novel submicron particle to facilitate ocular penetration of loteprednol etabonate in key anterior segment tissues (i.e., iris/ciliary body, aqueous humor and cornea). If approved, submicron loteprednol etabonate ophthalmic gel, 0.38% would be the lowest concentration loteprednol etabonate ophthalmic corticosteroid formulation indicated for the treatment of postoperative inflammation and pain following ocular surgery.

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 the Company's most recent annual or quarterly report and detailed from time to time in the Company's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. The Company believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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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