FDA Approves Prolensa

Bausch + Lomb Receives FDA Approval for Prolensa

MADISON, NJ - Bausch + Lomb, the global eye health company, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's New Drug Application (NDA) for Prolensa (bromfenac ophthalmic solution) 0.07 percent prescription eye drop, an innovative 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 will be available in 1.6ml and 3ml bottle sizes.

Prolensa provides powerful and rapid resolution of inflammation and pain by leveraging the unique potency of the bromfenac molecule in a formulation designed to facilitate ocular penetration. The advanced formulation allows for a lower concentration of bromfenac in a once daily dosing regimen. Prolensa is a solution that does not require shaking to deliver a consistent dose in each drop.

"The data show that once-daily dosing with Prolensa provides powerful and rapid control of inflammation and pain following cataract surgery, confirming the potency of this NSAID and the benefits of the new formulation," said Steven M. Silverstein, M.D., FACS, founder of Silverstein Eye Centers in Kansas City, MO. "Prolensa reduces the amount of medication placed on the healing eye while maintaining a high degree of efficacy and ocular comfort."

The efficacy of Prolensa was evaluated in two randomized, double-masked, vehicle-controlled studies of patients undergoing cataract surgery. Each randomized patient received Prolensa or vehicle starting with one drop into the surgical eye on the day prior to and the day of surgery, and for 14 days following surgery. The primary efficacy endpoint was complete clearing of ocular inflammation (assessed by the summed ocular inflammation score, SOIS, which includes cells and flare) by day 15. The secondary efficacy endpoint was the number of subjects that were pain free on day one after surgery.

Results from the pivotal studies demonstrated Prolensa to be superior to vehicle in the treatment of both inflammation and pain following cataract surgery. Twice as many patients as vehicle (46 percent versus 20 percent) demonstrated complete clearance of inflammation (SOIS of 0) at day 15. The difference in the average post-operative inflammation severity between the treatment and vehicle arms was statistically and clinically significant by day eight. Nearly four of five patients treated with Prolensa were pain free at day one (78.8 percent versus 49.5 percent for vehicle; $p<0.0001$). Patients treated with Prolensa reported a lower incidence of foreign body sensation and photophobia and had less redness than those treated with vehicle.

"Bausch + Lomb is committed to delivering innovative therapeutic options to eye care professionals and the patients they serve, and the advanced formulation used for Prolensa embodies that commitment," said Dan Wechsler, executive vice president and president, Bausch + Lomb Global Pharmaceuticals. "We look forward to bringing this next evolution of the groundbreaking bromfenac franchise to our customers very soon."

Prolensa 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

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity

- 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.

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.

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Prolensa (bromfenac) FDA Approval History