

Home > ... > Newsroom > 2012 archive > Bausch + Lomb Submits New Drug Application For Once-Daily PROLENSA™ To Treat Ocular Inflammation And Pain Following Cataract Surgery

[Tweet](#) [RSS](#)

FOR RELEASE 6/18/2012, Monday

Bausch + Lomb Submits New Drug Application for Once-Daily PROLENSA™ to Treat Ocular Inflammation and Pain Following Cataract Surgery

MADISON, N.J. — Bausch + Lomb, the global eye health company, announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for PROLENSA™ (bromfenac ophthalmic solution), a once-daily topical nonsteroidal anti-inflammatory compound for the treatment of ocular inflammation and pain following cataract surgery. PROLENSA, developed by recently acquired ISTA Pharmaceuticals, Inc., incorporates a lower concentration of bromfenac than the currently available once-daily BROMDAY™ (bromfenac ophthalmic solution) 0.09 percent, in a new formulation.

"The new, optimized formulation used for PROLENSA allows for a lower concentration of bromfenac, while maintaining the convenience of once-daily use currently prescribed with BROMDAY," stated Calvin Roberts, M.D., executive vice president, chief medical officer, Bausch + Lomb. A patent for PROLENSA's formulation and method of use, expiring in 2025, was recently issued to the licensor, Senju Pharmaceutical Co. Ltd., by the United States Patent and Trademark Office.

"The PROLENSA filing is an important step towards bringing safe, effective and meaningful medical advances to medical professionals and their patients," said Marvin Garrett, vice president of U.S. Regulatory Affairs, Quality Assurance and Compliance, Bausch + Lomb. "It's also a timely example of the progress we continue to make on critical D&R programs as we work to bring together the best of ISTA Pharmaceuticals and Bausch + Lomb."

About PROLENSA™

PROLENSA (bromfenac ophthalmic solution) is being developed as a once-daily topical nonsteroidal anti-inflammatory compound for the treatment of ocular inflammation and pain following cataract surgery. PROLENSA incorporates a lower concentration of bromfenac than the company's current once-daily NSAID, BROMDAY (bromfenac ophthalmic solution) 0.09 percent in a new formulation. From 2005 until 2011, ISTA Pharmaceuticals, Inc. marketed XIBROM (bromfenac ophthalmic solution) 0.09 percent in the U.S. for twice-daily use for the treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract surgery. In October of 2010, ISTA received FDA approval for once-daily BROMDAY, and the company discontinued shipments of XIBROM in February 2011. ISTA acquired U.S. ophthalmic rights to bromfenac in May 2002 under a license from Senju Pharmaceuticals Co. Ltd. On June 6, 2012, Bausch + Lomb acquired ISTA Pharmaceuticals, Inc.

BROMDAY is currently the only once daily treatment option in the \$370 million U.S. ophthalmic nonsteroidal anti-inflammatory market. PROLENSA is an investigational drug and not yet available for commercial use.

About Bausch + Lomb

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Its core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, the company is headquartered in Rochester, N.Y., and employs more than 11,000 people worldwide. Its products are available in more than 100 countries. More information is available at www.bausch.com.

###

News Media Contacts:

Teresa Panas
Bausch + Lomb Pharmaceuticals
+1 973-360-6382 or teresa.panas@bausch.com

Tad Heitmann
BioComm Network
+1 714-273-2937 or theitmann@BioCommNetwork.com

News - Related Links

- [Media Contacts](#)
- [2014 Archive](#)
- [2013 Archive](#)
- [2012 Archive](#)
- [2011 Archive](#)
- [2010 Archive](#)
- [2009 Archive](#)
- [2008 Archive](#)
- [2007 Archive](#)

Vision and Eye Health

- [Vision and Age](#)
- [Eye Infections & Irritations](#)
- [Diseases and Disorders](#)
- [Find a Doctor](#)
- [PDF Eye Exam Check List](#)

Products

- [Contact Lenses](#)
- [Contact Lens Care](#)
- [Dry Eye Products](#)
- [Allergy/Redness Relief](#)
- [Rx Pharmaceutical](#)

Customer Support

- [Contact Us](#)
- [Customer policies and forms](#)
- [Rebate Center](#)
- [Worldwide Locations](#)

Legal

- [Legal Notice](#)
- [Privacy Policy](#)
- [Material Safety Data Sheets](#)

Newsroom

- [Careers](#)
- [Investor Relations](#)
- [Grants & Contributions](#)

Eye Vitamins
Surgical Products
Vision Accessories

© 2015 Bausch & Lomb Incorporated.

All information and materials on his site pertain to the U.S. only, unless o herwise indicated.