

**FOR IMMEDIATE RELEASE**

## **Sun Pharma launches first branded ophthalmic product, BromSite™, in USA**

***BromSite™ launch is a significant milestone for Sun Pharma in USA***

*Product to be marketed by Sun Ophthalmics*

*Dedicated marketing & sales team for optimal customer service*

*BromSite™ is the first NSAID approved by the USFDA for prevention of ocular pain & treatment of inflammation following cataract surgery*

**MUMBAI (INDIA) & NEW JERSEY (USA) - November 28, 2016:** Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies) today announced the launch of BromSite™ (bromfenac ophthalmic solution) 0.075% in the US market. A nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery, BromSite™ will be marketed by Sun Ophthalmics, the company's branded ophthalmic business division. BromSite is the first branded product launched by the company in the USA, following its focus on Specialty Business.

Approved by the USFDA on April 8, 2016, BromSite™ (bromfenac ophthalmic solution) 0.075% is the first NSAID approved to prevent ocular pain and treat inflammation in the eye following cataract surgery. Developed by California-based InSite Vision, a subsidiary of Sun Pharma, it is also the first bromfenac ophthalmic solution formulated in DuraSite™, a polymer-based drug delivery system that is used to improve drug solubility, absorption, bioavailability, and residence time as compared to conventional topical therapies.

**Commenting on the launch of BromSite, Abhay Gandhi, CEO – North America Business, Sun Pharma said,** "As the first branded ophthalmic product launched by Sun Ophthalmics business division, BromSite™'s launch is a significant milestone for Sun Pharma in the USA. Clinical studies have reinforced BromSite's strong safety and efficacy profile in cataract surgery patients, culminating in this FDA indication for the prevention of ocular pain following surgery. We are confident BromSite™ will prove itself a quality treatment option for cataract surgeons and their patients. Furthermore, with several promising candidates in our Ophthalmics pipeline, Sun Ophthalmics is positioned to provide eye care professionals additional, quality treatment options in the near future."

*"This is an exciting, important moment for Sun Ophthalmics," said Jerry St. Peter, Vice President & Head - Sun Ophthalmics. "The BromSite™ launch marks not only the unveiling of our first brand, but the entry of a new, robust sales force and marketing team dedicated to optimal customer service. We are committed to providing products that enhance doctors' practice patterns and treatment options, as well as delivering these products through a talented, knowledgeable, and responsive commercial team. BromSite™ is our first opportunity to prove that commitment to eye care professionals."*

As part of its Patient Access Program (PAP), Sun Ophthalmics is committed to making BromSite™ available to all patients. The company will offer patient assistance wherever required.

**According to Dr. Richard L. Lindstrom, MD, Founder and attending surgeon of Minnesota Eye Consultants and Adjunct Professor Emeritus at the University of Minnesota, Department of Ophthalmology.** *"I am pleased that BromSite™ is now available to eye care practitioners. Multiple clinical studies have demonstrated the drug's efficacy in preventing ocular pain and reducing inflammation in patients undergoing cataract surgery. These clinical results, in combination with BromSite™'s unique label to prevent ocular pain, will make it a welcome addition to cataract surgeons' armamentarium."*

### **About BromSite™ (bromfenac ophthalmic solution) 0.075%**

BromSite™ is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.

### **IMPORTANT SAFETY INFORMATION**

- **Slow or Delayed Healing:** All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including BromSite™ (bromfenac ophthalmic solution) 0.075%, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- **Potential for Cross-Sensitivity:** There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including BromSite™ (bromfenac ophthalmic solution) 0.075%. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.
- **Increased Bleeding Time of Ocular Tissue:** With some NSAIDs, including BromSite™ (bromfenac ophthalmic solution) 0.075%, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. It is recommended that BromSite™ be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.
- **Use of topical NSAIDs may result in keratitis:** Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including BromSite™ (bromfenac ophthalmic solution) 0.075%, and should be closely monitored for corneal health.

Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post surgery may increase patient risk for the occurrence and severity of corneal adverse events.

- **BromSite™ should not be administered while wearing contact lenses:** The preservative in BromSite™, benzalkonium chloride, may be absorbed by soft contact lenses.
- The most commonly reported adverse reactions in 1% to 8% of patients were anterior chamber inflammation, headache, vitreous floaters, iritis, eye pain, and ocular hypertension.

Please see [Full Prescribing Information](#) for additional important safety information.

Please also see [www.bromsite.com](http://www.bromsite.com) for more information.

**About Sun Ophthalmics:** Backed by Sun Pharma's global expertise in R&D, Sun Ophthalmics (the branded ophthalmics division of Sun Pharma) is leading the way through development of innovative products and in partnership with eye care professionals. Sun Ophthalmic's BromSite™ (bromfenac ophthalmic solution) 0.075%, currently available in the US, is indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. Candidates in Sun Ophthalmics development pipeline include Xelpros™ (latanoprost ophthalmic solution) 0.005%, being explored for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension, and DexaSite™ (dexamethasone) 0.1%, being explored for the treatment of blepharitis. Recently, with Sun Pharma's announced acquisition of Ocular Technologies, SARL, Sun Ophthalmics expanded its pipeline to include Seceira, a cyclosporine A-based drug undergoing clinical trials for the treatment of dry eye disease. Sun Ophthalmics' dedicated team is focused solely on the needs of eye care professionals, offering timely, knowledgeable support at every turn. It is striving to deliver products built on unique platforms that integrate seamlessly into the eye care practice, helping eye care professionals to continue providing quality medicine. Discover a brighter future in eye care at [www.sunophthalmics.com](http://www.sunophthalmics.com)

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**About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):**

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 47 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes US\$ 2.1 billion. In India, the Company enjoys leadership across 12 different classes of doctors with 32 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 8% of annual revenues. For further information please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live

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