



**FOR IMMEDIATE RELEASE**

## **Sun Pharma Receives USFDA Approval For BromSite™**

*First NSAID approved for prevention of ocular pain in patients undergoing cataract surgery*

**Mumbai, April 09, 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 that one of its wholly owned subsidiaries has received approval from USFDA for its New Drug Application (NDA) related to BromSite™ (bromfenac ophthalmic solution) 0.075% for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. BromSite™ is the first non-steroidal anti-inflammatory drug (NSAID) approved by the USFDA to prevent pain and treat inflammation in the eye for patients undergoing cataract surgery; other NSAIDs in this class are currently indicated for the treatment of inflammation and reduction of pain.

BromSite™ developed by InSite Vision, is the first bromfenac ophthalmic solution formulated in DuraSite™, a polymer-based formulation that can be used to improve solubility, absorption, bioavailability, and residence time as compared to conventional topical therapies. Sun Pharma acquired InSite Vision in November 2015 and is likely to commercialize BromSite™ through its newly formed, US-based division, Sun Ophthalmics, in the second half of 2016. As per IMS MAT January 2016, the U.S. NSAID Ophthalmic market grew by 8%, generating approximately US\$400mn in sales and about 4 million prescriptions, providing an attractive market for Sun Pharma to participate.

Sun Ophthalmics has crossed a key business milestone through BromSite's approval. Sun Ophthalmics targets to provide eye care practitioners products that enhance their practice patterns and treatment options and to deliver those products through its unique, concierge level approach to customer care. With BromSite's approval and additional late-stage candidates in its pipeline, Sun Ophthalmics is strongly positioned to offer a range of beneficial products and establish itself as a respected and trusted partner.

In two multi-center, randomized, placebo-controlled Phase-3 studies, a significantly higher proportion of BromSite-treated patients were pain-free at Day 1 post-surgery (77% and 82%) compared to patients treated with vehicle control (48% and 62%) ( $p < 0.001$ ). Additionally, a significantly higher proportion of subjects administered BromSite™ were inflammation-free at day 15 post-cataract surgery (57% and 38%), compared to a vehicle control group (19% and 22%) ( $p < 0.001$  and  $p = 0.035$ ).

"Over the years, I've worked closely with the InSite team and watched them develop multiple high quality products using the DuraSite platform," commented 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. "Today, I am pleased to see BromSite™ advance from development to market. I am confident there will be significant clinician interest in this new product. As the first NSAID labeled to prevent pain and reduce inflammation post-cataract surgery, BromSite's approval is timely and will be welcomed by patients and clinicians alike."

### **About Sun Ophthalmics**

Sun Ophthalmics is likely to launch BromSite™ (bromfenac ophthalmic solution) 0.075% in US in second half of 2016, indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. Other pipeline candidates 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. Sun Ophthalmics is based in Princeton, NJ.

Sun Pharmaceutical Industries Ltd.  
SUN HOUSE, CTS No. 201 B/1,  
Western Express Highway, Goregaon (E),  
Mumbai 400063, India  
Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343  
CIN: L24230GJ1993PLC019050  
www.sunpharma.com



**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 49 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 2015 were approximately US\$ 4.5 billion, of which US contributed US\$ 2.2 billion. In India, the company enjoys leadership across 12 different classes of doctors with 30 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 7% of annual revenues. For further information please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live.

**Contacts**

**USA**

Corporate Contact  
Sanjay Malieckal  
Tel Direct +1 732 754-6979  
E mail Sanjay.Malieckal@sunpharma.com

Media Contact  
Mike Elofer – Pascale Communications  
Tel Direct +1 484 620-6167  
E mail mike@pascalecommunications.com

**India**

Nimish Desai  
Tel +91 22 4324 4324, Xtn 2778  
Tel Direct +91 22 4324 2778  
Mobile +91-98203 30182  
E mail nimish.desai@sunpharma.com

Frederick Castro  
Tel +91 22 4324 4324, Xtn 2777  
Tel Direct +91 22 4324 2777  
Mobile +91 99206 65176  
E mail frederick.castro@sunpharma.com