

Sun Pharma receives FDA approval for BromSite

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Sun Pharma has 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.

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.

"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," he added.