



Sun Pharma and SPARC Announce US FDA Approval of XELPROS™ to Treat Open-angle Glaucoma or Ocular Hypertension

XELPROS™ (latanoprost ophthalmic emulsion) 0.005% for topical ophthalmic use is the first and only benzalkonium chloride-free (BAK-free) form of latanoprost

Mumbai, India, Princeton, NJ, September 14, 2018 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) and Sun Pharma Advanced Research Company Ltd. (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872, "SPARC") today announced U.S. Food and Drug Administration (USFDA) approval for the New Drug Application (NDA) of XELPROS™ (latanoprost ophthalmic emulsion) 0.005% for the reduction of elevated intraocular pressure (IOP, or pressure inside the eye) in patients with open-angle glaucoma or ocular hypertension. This approval is from Sun Pharma's Halol (Gujarat, India) facility.

Sun Pharma in-licensed XELPROS™ from SPARC in June 2015 and this approval will trigger a milestone payment to SPARC. SPARC is also eligible for milestone payments and royalties on commercialization of XELPROS™ in the US.

XELPROS™ is the first and only form of latanoprost that is not formulated with benzalkonium chloride (BAK), a preservative commonly used in topical ocular preparations. XELPROS™ is developed using SPARC's proprietary Swollen Micelle Microemulsion (SMM) technology.

"As the only BAK-free version of latanoprost, XELPROS™ will be an important and alternative treatment option for individuals with open-angle glaucoma or ocular hypertension," said Abhay Gandhi, CEO, North America, Sun Pharma. "This approval, coming less than one month following the approval of [CEQUA™](#) (cyclosporine ophthalmic solution) 0.09%, reaffirms the strength of Sun Pharma's fast-growing Ophthalmics division and its commitment to serving the needs of patients with ocular disorders."

Anil Raghavan, CEO, SPARC said, "Approval of XELPROS™ by USFDA is a significant milestone for SPARC. It is also a validation of our SMM technology which helps to solubilize drugs that have limited or no solubility thus eliminating the need for benzalkonium chloride (BAK)."

In randomized, controlled clinical trials of patients with open-angle glaucoma or ocular hypertension with a mean baseline Intraocular pressure (IOP) of 23-26 mmHg, XELPROS™ lowered IOP by a mean of up to 6-8 mmHg.

XELPROS™ will be commercialized in the U.S. by Sun Ophthalmics, the branded ophthalmic division of Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary.



About XELPROS™

XELPROS™ (latanoprost ophthalmic emulsion) 0.005%, a translucent ophthalmic emulsion, is a topical formulation of latanoprost, a prostaglandin analogue that is used as first-line treatment for open-angle glaucoma or ocular hypertension. It is the first and only BAK-free form of latanoprost. The recommended dosage of XELPROS™ is one drop in the affected eye(s) once daily in the evening. If one dose is missed, treatment should continue with the next dose as normal. Reduction of IOP starts approximately 3 to 4 hours after administration and the maximum effect is reached after 8 to 12 hours.

Across multiple XELPROS™ clinical trials, the most frequently reported ocular adverse reactions were eye pain/stinging upon instillation and ocular hyperemia (redness), reported in 55% and 41% of patients treated with XELPROS™, respectively. Less than 1% of patients discontinued therapy because of intolerance to these adverse events.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XELPROS™ is contraindicated in patients with known hypersensitivity to latanoprost, or any other ingredients in this product.

WARNINGS AND PRECAUTIONS

Pigmentation: XELPROS™ may cause changes to pigmented tissues. The most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as XELPROS™ is administered. After discontinuation of XELPROS™ iris pigmentation is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Eyelash Changes: XELPROS™ may gradually cause changes to eyelashes, vellus hair in the treated eye including increased length, thickness, pigmentation and number of lashes. The changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: XELPROS™ should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

Macular Edema: XELPROS™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.



Herpetic Keratitis: XELPROS™ should be used with caution in patients with a history of herpetic keratitis. XELPROS™ should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Bacterial Keratitis: There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lens: Contact lenses should be removed prior to administration of XELPROS™ and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS

The most common ocular adverse reactions reported in clinical trials (incidence $\geq 5\%$) for XELPROS™ are: eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening.

DRUG INTERACTIONS

Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROS™. If such drugs are used, they should be administered at least five (5) minutes apart.

Please click here for [Full Prescribing Information](#) & for more information visit www.MyXelpros.com

About Open-angle Glaucoma

Open-angle glaucoma (also known as primary or chronic glaucoma) is the most common form of glaucoma, accounting for more than 90% of cases. It is caused by clogging of the drainage canals in the eye, resulting in elevated intraocular pressure (IOP). A lifelong condition, open-angle glaucoma develops slowly, causing ocular nerve damage that gradually affects a patient's visual function.

In the U.S., glaucoma is a leading cause of irreversible blindness, second only to macular degeneration. More than 2.25 million Americans older than 40 years have open-angle glaucoma. Worldwide, glaucoma is the second leading cause of blindness, surpassed only by cataracts; more than 2 million people around the world will develop open-angle glaucoma each year, and more than 3 million are bilaterally blind (i.e., in both eyes) from open-angle glaucoma¹.



About Ocular Hypertension

Ocular hypertension is a condition in which IOP is greater than 21 mmHg, the widely accepted upper limit of normal IOP in the general population. In individuals with ocular hypertension, fluid from the front of the eye does not drain properly, causing IOP to build up. Although ocular hypertension can cause glaucoma, it is not the same as glaucoma; with ocular hypertension, the optic nerve appears normal and there are no signs of vision loss. However, individuals with ocular hypertension are considered "glaucoma suspects," and should visit their ophthalmologist regularly to be checked for glaucoma. Population studies in various countries suggest that ocular hypertension affects an estimated 4-10% of individuals older than 40 years. The prevalence of ocular hypertension is 10-15 times greater than that of open-angle glaucoma.

References

1. Biggerstaff KS. Primary open-angle glaucoma (POAG). Medscape, 2018. <https://emedicine.medscape.com/article/1206147-overview#a6>. Accessed September 5, 2018.

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About Sun Ophthalmics

Backed by Sun Pharma's global expertise in R&D, Sun Ophthalmics (the branded ophthalmic division of Sun Pharma's wholly owned subsidiary) is leading the way through the development of innovative products and in partnership with eye care professionals. In the U.S., Sun Ophthalmics market BromSite[®] (bromfenac ophthalmic solution) 0.075%, and will soon commence marketing [CEQUA[™]](#) (cyclosporine ophthalmic solution) 0.09% and XELPROS[™] (latanoprost ophthalmic solution) 0.005%, both of which were recently approved by the USFDA. Sun Ophthalmics' dedicated team is focused solely on the needs of eye care professionals, offering timely, knowledgeable support at every turn. The company strives 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.



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 42 manufacturing facilities spread across 6 continents, R&D centers across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 13 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 3 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 approximately 8% of annual revenues. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

About Sun Pharma Advanced Research Company Ltd. (CIN - L73100GJ2006PLC047837):

Sun Pharma Advanced Research Company Ltd. (SPARC) is a clinical stage bio-pharmaceutical company focused on continuously improving standards of care for patients globally, through innovation in therapeutics and delivery. SPARC aims to consistently lower costs and improve operational efficiencies to advance availability and affordability of cures for patients across the world. More information about the company can be found at www.sparc.life



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