

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces US FDA Acceptance of NDA for OTX-101**

*OTX-101 is being evaluated for treatment of dry eye disease*

*Phase 3 Confirmatory Study Data Demonstrated Potential of OTX-101 to Offer Patients Improved Tear Production Coupled With Faster Onset of Action*

*Sun Pharma is developing OTX-101 for global markets*

Mumbai, India, December 27, 2017: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) announces that the US FDA has accepted a New Drug Application (NDA), filed by its wholly owned subsidiary, for OTX-101 (cyclosporine A, ophthalmic solution) 0.09%, a novel nanomicellar formulation of cyclosporine A 0.09% in a clear, preservative-free aqueous solution. OTX-101 is now under review for approval by the US FDA, marking an important developmental milestone for Sun Pharma's dry eye candidate.

**Dilip Shanghvi, Managing Director, Sun Pharma,** said: "Dry Eye disease is a complex, chronic condition that affects patient quality of life, often significantly. OTX-101, a novel formulation of cyclosporine, will allow us to participate in the rapidly growing underserved and dynamic Dry Eye market. When approved, it will be a milestone for millions of Dry Eye patients across the globe that are yet to find relief for their condition."

Post the US FDA approval, OTX-101 will be commercialized in the US by Sun Ophthalmics, the branded ophthalmics division of Sun Pharma's wholly owned subsidiary, based in Princeton, New Jersey. Sun Ophthalmics, founded in 2015, currently markets BromSite® (bromfenac ophthalmic solution) 0.075% to eye care practitioners across US.

**Commenting on the development Abhay Gandhi, CEO - North America Business, Sun Pharma,** said, "We are excited about the acceptance of this filing by the US FDA. In January 2017, we had announced positive topline results of confirmatory Phase-3 clinical trial for OTX-101, demonstrating both efficacy and faster onset of action in a trial environment. The 12 week trial saw 744 dry eye patients being treated either with OTX-101, or its vehicle. Compared to the vehicle, OTX-101 showed statistically significant improvement in the primary end point in the trial. The demonstration of efficacy of OTX-101 was earlier than other drugs approved for dry eye in the same class<sup>1</sup>. We hope to bring OTX-101 to patients in the United States as soon as possible, and look forward to working closely with the US FDA over the coming months."

### **About OTX-101**

OTX-101 is being evaluated for the treatment of dry eye disease. It is a patented, novel, proprietary nanomicellar formulation of cyclosporine A, 0.09%. It is a clear, preservative-free, aqueous solution. In a 12 week, multicenter, randomized, double-masked, vehicle controlled Phase 3 confirmatory study, 744 dry eye patients were treated either with OTX-101, or its vehicle. After 12 weeks of treatment, as compared to vehicle, OTX-101 showed

statistically significant improvement in the primary end point, Schirmer's score (a measurement of tear production) ( $p < 0.0001$ ). The demonstration of efficacy by OTX-101 at 12 weeks is earlier than other drugs approved for dry eye in the same class.<sup>1</sup>

Additionally, several key secondary endpoints showed statistically significant improvements compared to vehicle with some showing an even earlier onset of action. Adverse events reported in the trial were mild to moderate in nature and similar to other approved drugs in the category.<sup>1-3</sup> As Sun continues to analyze the data, additional significant findings will be shared at upcoming medical conferences.

Previously, in a completed Phase 2b/3 clinical trial in 455 patients, OTX-101 demonstrated a rapid onset of action and was well tolerated by the study population. Based on published data, the efficacy and safety endpoints in these trials compared favorably to other formulations of cyclosporine A with the advantage of faster onset.<sup>1</sup>

### **About Dry Eye Disease**

Dry Eye Disease, as defined by the National Health Institute (NHI), occurs when the eye does not produce tears properly, or when the tears are not of the correct consistency and evaporate too quickly. In addition, inflammation of the surface of the eye may occur along with dry eye. If left untreated, this condition can lead to pain, ulcers, or scars on the cornea, and some loss of vision. Dry eye can make it more difficult to perform some activities, such as using a computer or reading for an extended period of time, and it can decrease tolerance for dry environments, such as the air inside an airplane. Other names for dry eye include dry eye syndrome, keratoconjunctivitis sicca (KCS), dysfunctional tear syndrome, lacrimal keratoconjunctivitis, evaporative tear deficiency, aqueous tear deficiency, and LASIK-induced neurotrophic epitheliopathy (LNE).

### **About Sun Ophthalmics**

Backed by Sun Pharma's global expertise in R&D, Sun Ophthalmics (the branded ophthalmics 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. Sun Ophthalmics markets BromSite® (bromfenac ophthalmic solution) 0.075% in the US. Other candidates in Sun Ophthalmics' development pipeline include Xelpros™ (latanoprost ophthalmic solution) 0.005% and DexaSite™ (dexamethasone) 0.1%. 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 fourth 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 41 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 11 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 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](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live

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