

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces Positive Topline Results of Confirmatory Phase-3 Clinical Trial for Seciera™ for Treatment of Dry Eye**

*Seciera™ Meets Primary and Key Secondary Endpoints in Pivotal Trial*

*Shows efficacy at 12 weeks of treatment*

*Sun Pharma is developing Seciera™ for global markets*

**MUMBAI (India), January 4, 2017:** Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies), announced successful Phase 3 confirmatory clinical trial results for Seciera™ (cyclosporine A, 0.09% ophthalmic solution), for the treatment of dry eye disease. Seciera™ is a patented, novel, proprietary nanomicellar formulation of cyclosporine A 0.09%. It is a clear, preservative-free, aqueous solution. Seciera™ is being developed by Ocular Technologies, a company recently acquired by Sun Pharma. Following this acquisition, Sun Pharma owns exclusive, worldwide rights to Seciera™ and is developing it to commercialize for global markets including US, Europe, and Japan, as well as several emerging markets.

In this 12 week, multicenter, randomized, double-masked, vehicle controlled Phase 3 confirmatory study, 744 dry eye patients were treated either with Seciera™, or its vehicle. After 12 weeks of treatment, as compared to vehicle, Seciera™ 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 Seciera™ 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, Seciera™ 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 early onset.<sup>1</sup>

**According to Dilip Shanghvi, Managing Director, Sun Pharma,** "We are happy to see the early onset of action and strong efficacy results for Seciera™. These results are highly encouraging for millions of Dry Eye patients<sup>4-6</sup> across the globe that have yet to find relief for their condition. We look forward to discussing these results with US FDA and agree on next steps for the program."

"I am very excited to see these strong results for Seciera™," **noted Dr. Joseph Tauber, Study Investigator and founder of the Tauber Eye Center, Kansas City, Missouri.** "As a clinician who specializes in diagnosing and treating dry eye, this novel formulation of cyclosporine A would be a unique and welcome addition to our armamentarium to treat these patients".

**Jerry St. Peter, Vice President and Head of Sun Ophthalmics, added:** "A key strategic imperative for our ophthalmic business is to participate in the rapidly growing, underserved, and dynamic Dry Eye market, which is expected to reach \$5 billion by 2020.<sup>7</sup> Based on this successful confirmatory Phase 3 trial, Seciera™ has the potential to strengthen our emerging ophthalmics pipeline, which includes the recent launch of BromSite™ and late stage development programs for Xelpros™ and DexaSite™."

#### **References:**

1. Sall K, Stevenson OD, Mundorf TK, Reis BL. Two multicenter, randomized studies of the efficacy and safety of cyclosporine ophthalmic emulsion in moderate to severe dry eye disease. CsA Phase 3 Study Group. *Ophthalmology*. 2000 Apr;107(4):631-9. PMID: 10768324
2. Sheppard JD, Torkildsen GL, Lonsdale JD, D'Ambrosio FA Jr, McLaurin EB, Eiferman RA, Kennedy KS, Semba CP. Lifitegrast ophthalmic solution 5.0% for treatment of dry eye disease: results of the OPUS-1 phase 3 study. *Ophthalmology*. 2014 Feb;121(2):475-83. doi: 10.1016/j.ophtha.2013.09.015. Epub 2013 Nov 26. PMID: 24289915
3. Tauber J, Karpecki P, Latkany R, Luchs J, Martel J, Sall K, Raychaudhuri A, Smith V, Semba CP. Lifitegrast Ophthalmic Solution 5.0% versus Placebo for Treatment of Dry Eye Disease: Results of the Randomized Phase III OPUS-2 Study. *Ophthalmology*. 2015 Dec;122(12):2423-31. doi: 10.1016/j.ophtha.2015.08.001. Epub 2015 Sep 11. PMID: 26365210
4. DEWS Research Subcommittee. Research in dry eye: report of the Research Subcommittee of the International Dry Eye WorkShop (2007). *Ocul Surf*. 2007;5(2):179-193.
5. Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the Beaver Dam Offspring Study: prevalence, risk factors, and health-related quality of life. *Am J Ophthalmol*. 2014;157(4):799-806.
6. Kantar Health. National Health and Wellness Survey: The Global Health and Wellness Report – 2014. <http://www.kantarhealth.com/docs/ebooks/global-health-and-wellness-report.pdf>. Accessed May23, 2016.
7. Market Scope - 2015 Comprehensive Report on the Global Dry Eye Products Market; December 2015

#### **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).

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 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 recently launched BromSite™ (bromfenac ophthalmic solution) 0.075% in US for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. Other candidates in Sun Ophthalmics development pipeline include Xelpros™ (latanoprost 0.005% ophthalmic solution), 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' 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)

### **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

### **Safe Harbor:**

Statements in this document describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

### **For More Information Please Contact**

#### **Sun Pharma**

#### **Investors Contact**

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](mailto:nimish.desai@sunpharma.com)

#### **Media Contact**

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](mailto:frederick.castro@sunpharma.com)

#### **For Media In USA**

Michele Gray – Gray Communications

Tel Direct +1 917 449-9250  
E mail [michele\\_gray@me.com](mailto:michele_gray@me.com)