

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



**16 August 2018.**

National Stock Exchange of India Ltd,  
Exchange Plaza, 5th Floor,  
Plot No. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai – 400 051.

BSE Limited,  
Market Operations Dept.  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai - 400 001.

Dear Sirs,

**Sub: Press Release**

We are pleased to enclose herewith our Press Release relating to USFDA Approval of CEQUA™, which we shall be releasing after sending this letter to you. This is for your information and record.

Thanking you,

Yours faithfully,  
For Sun Pharmaceutical Industries Ltd

A handwritten signature in blue ink, appearing to read "A. I. Bhuta".

Ashok I. Bhuta  
Compliance Officer

Encl: as above

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



**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces U.S. FDA Approval of CEQUA™ to Treat Dry Eye Disease**

*CEQUA (cyclosporine ophthalmic solution) 0.09% for topical ophthalmic use is the first and only dry eye treatment to combine cyclosporine A with nanomicellar technology*

**Mumbai, India, Princeton, NJ, August 16, 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) today announced that Sun Pharma has received approval for CEQUA (cyclosporine ophthalmic solution) 0.09%, from the U.S. Food and Drug Administration (FDA). CEQUA is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

CEQUA provides the highest FDA-approved concentration of cyclosporine A (CsA) and is the first and only approved CsA product that incorporates a nanomicellar technology. The innovative nanomicellar formulation allows the CsA molecule to overcome solubility challenges, penetrate the eye’s aqueous layer and prevents the release of the active lipophilic molecule prior to penetration. In the Phase 3 confirmatory trial on CEQUA, after 12 weeks of treatment, as compared to vehicle, CEQUA showed statistically significant improvement in the primary endpoint, Schirmer’s score (a measurement of tear production) ( $p < 0.01$ ). Improvements in secondary endpoints (i.e. ocular staining assessments) were seen as early as 1 month after initiating treatment. CEQUA is dosed twice daily and will be available as a single-use vial.

The nanomicellar formulation technology uses micelles, which are gelatinous aggregates of amphipathic (both hydrophobic and hydrophilic) molecules formed at a well-defined concentration. The small size of the nanomicelles facilitates entry into corneal and conjunctival cells, enabling delivery of high concentrations of CsA.

“Dry Eye Disease represents an area of high unmet medical need, with a significant number of patients who are currently untreated,” said Abhay Gandhi, CEO, North America, Sun Pharma. “The U.S. FDA approval of CEQUA represents a long-awaited dry eye treatment option and is an important milestone in the development of Sun’s Ophthalmics business. CEQUA, with its novel nanomicellar formulation for a proven dry eye medication, delivers a lipophilic molecule in a clear solution form.”

Additionally, Jodi Luchs, MD, the principal investigator behind the CEQUA confirmatory Phase 3 trial, noted: “Dry eye is a complex disease that lacks a ‘one-size-fits-all’ approach. As a clinician treating a high volume of dry eye patients, it’s important to have multiple treatment modalities available at my disposal. Given its strong clinical trial performance, the approval of CEQUA is welcomed news, and I look forward to offering my patients this compelling new option.”

Registered Office : SPARC, Tandalja, Vadodara – 390 012. India

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



CEQUA (cyclosporine ophthalmic solution) 0.09%, for topical ophthalmic use will be commercialized in the U.S. by Sun Ophthalmics, the branded ophthalmics division of Sun Pharma's wholly owned subsidiary.

### **About CEQUA™**

CEQUA (cyclosporine A, ophthalmic solution) is a patented, novel, proprietary nanomicellar formulation of cyclosporine A, 0.09% in a clear, preservative-free, aqueous solution. In a multicentered, randomized, double-masked, vehicle-controlled Phase 3 confirmatory study, 744 patients with dry eye were treated either with CEQUA or its vehicle. After 12 weeks of treatment, as compared to vehicle, CEQUA showed statistically significant improvement in the primary end point, Schirmer's score (a measurement of tear production) ( $p < 0.01$ ). Additionally, several key secondary endpoints showed statistically significant improvements compared to vehicle, with some showing improvement as early as 1 month following treatment. Adverse events reported in the trial were mostly mild in nature. In a prior Phase 2b/3 clinical trial with 455 patients, CEQUA demonstrated increased tear production ( $p < 0.01$ ) and was well tolerated by the study population. Additionally, several key secondary endpoints showed statistically significant improvements compared to vehicle. The most common adverse reaction following the use of cyclosporine ophthalmic solution 0.09% was instillation site pain (22%) and conjunctival hyperemia (6%). Other adverse reactions reported in 1% to 5% of the patients were eye irritation, blepharitis urinary tract infection, headache, and bronchitis.

### **INDICATIONS AND USAGE**

CEQUA (cyclosporine ophthalmic solution) 0.09% is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

### **IMPORTANT SAFETY INFORMATION**

#### **WARNINGS AND PRECAUTIONS**

**Potential for Eye Injury and Contamination:** To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces.

**Use with Contact Lenses:** CEQUA should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of CEQUA ophthalmic solution.

#### **ADVERSE REACTIONS**

The most common adverse reactions reported in greater than 5% of patients were pain on instillation of drops (22%) and conjunctival hyperemia (6%). Other adverse reactions reported in 1% to 5% of patients were blepharitis, eye irritation, headache, and urinary tract infection.

Please click for [Full Prescribing Information](#) & for more information visit [CEQUA.com](http://CEQUA.com)

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 Dry Eye Disease**

Dry eye is a burdensome, chronic disease affecting millions of patients around the world, with a significant population, greater than 16 million patients, present in the United States.

Dry eye disease, as defined by the National Eye Institute (NEI, a division of the U.S. National Institutes of Health [NIH]), occurs when the quantity and/or quality of tears fails to keep the surface of the eye properly lubricated. The disease causes a scratchy sensation or a feeling that something is in the eye. Other symptoms include stinging or burning, episodes of excess tearing following periods of stress, discharge, pain, and redness in the eye. The risk of developing dry eye increases with advancing age, and is more common in women than in men.

*TM - All brand names and trademarks are the property of respective owners.*

## **Disclaimer:**

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.

## **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 U.S. 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. 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](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 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 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

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



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.

### **Contacts: Sun Pharma**

#### **Investors:**

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:**

Gaurav Chugh  
Tel +91 22 4324 4324, Xtn 5373  
Tel Direct +91 22 4324 5373  
Mobile +91 98104 71414  
E mail [gaurav.chugh@sunpharma.com](mailto:gaurav.chugh@sunpharma.com)

#### **US Media:**

Reba Auslander  
Tel Direct +1 917-836-9308  
Email [reba@raliancecommunications.com](mailto:reba@raliancecommunications.com)