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**27 June 2019.**

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**

Please find enclosed herewith our Press Release relating to License Agreement with China Medical System Holdings for Cyclosporine A eye drops in Greater China, 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

**FOR IMMEDIATE RELEASE**

## **Sun Pharma and China Medical System Holdings enter into a License Agreement for Cyclosporine A eye drops in Greater China**

- *Relationship gives Sun Pharma access to dry eye market in Greater China*
- *Greater China to become a key market in future with more than 100 million<sup>1,2</sup> people currently suffering from dry eye disease*

**Mumbai, India June 27, 2019** – 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 one of its wholly owned subsidiaries has entered into an exclusive licensing agreement with a subsidiary of China Medical System Holdings Ltd. (CMS) for the development and commercialization of Cyclosporine A 0.09% (CsA) eye drops, an innovative formulation, for dry eye disease in Greater China (including Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan).

Under terms of the license agreement, CMS will pay Sun Pharma an initial upfront payment, regulatory and sales milestone payments, and royalties on net sales, the terms of which are confidential. CMS will be responsible for development, regulatory filings and commercialization of the product in China. The initial tenure of the agreement shall be 15 years from the first commercial sale of CsA in Greater China, and may be extended for additional 3 years subject to certain conditions defined in the agreement.

“We are pleased to enter into a licensing arrangement with CMS, a leading pharmaceutical company in Greater China. Dry Eye disease represents an area of high unmet medical need, with a significant number of patients having moderate to severe form of this disease. Sun Pharma is committed to growing its global ophthalmology franchise, with cyclosporine as its lead product.” said Kirti Ganorkar, Executive Vice President and Head, Global Business Development, Sun Pharma.

### **About Cyclosporine A 0.09% (CsA) eye drops**

Cyclosporine A 0.09% ophthalmic solution (CsA) is a patented, novel, proprietary nanomicellar formulation in a clear, preservative-free, aqueous solution. This nanomicellar 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. In a multicentered, randomized, double-masked, vehicle-controlled Phase 3 confirmatory study, 744 patients with dry eye were treated either with CsA or its vehicle. After 12 weeks of treatment, as compared to vehicle, CsA 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, CsA 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.

Sun Pharma acquired global rights and intellectual property for Cyclosporine A 0.09% ophthalmic solution through the acquisition of Ocular Technologies, Sarl, a portfolio company of Auve Therapeutics (Auve), an international private equity company. The product was approved by US FDA in August 2018 under the CEQUA™ brand name.

## **INDICATIONS AND USAGE**

Cyclosporine A 0.09% ophthalmic solution 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:** Cyclosporine A 0.09% ophthalmic solution 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 Cyclosporine A 0.09% 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.

### **About Dry Eye Disease**

Dry eye is a burdensome, chronic disease affecting millions of patients around the world, with a significant population, greater than 100 million<sup>1,2</sup> patients, present in Greater China. Dry eye disease 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.

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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 and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live

### **About CMS**

CMS is a well-established, innovation-driven specialty pharma company with focus on sales and marketing in China. CMS is committed to offering competitive products and services to meet China's unmet medical needs with a strong and professional sales and marketing network as well as a promotion platform covering the whole Chinese market. It is listed on the Hong Kong Stock Exchange (867.HK). For more information, please see <https://en.cms.net.cn/CmsNewWebEn/Index.aspx>

### **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.

### **References**

1. Experts' consensus about clinical diagnosis and treatment of dry eye, 2013
2. Prevalence, Burden, and Pharmacoeconomics of Dry Eye Disease

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