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FOR IMMEDIATE RELEASE

Sun Pharma Launches CEQUA for the Treatment of Dry Eye Disease in the U.S.

- *CEQUA™ (cyclosporine ophthalmic solution) 0.09% for topical ophthalmic use is the first and only approved cyclosporine treatment delivered with NCELL™ technology*

- *Sun Pharma introduces CEQUA SUPPORT™ Specialty Pharmacy program to enable easy access for patients to obtain treatment*

Mumbai, India & Princeton, NJ, October 14, 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 commercialized CEQUA (cyclosporine ophthalmic solution) 0.09% in the U.S. CEQUA, which offers the highest concentration of cyclosporine for ophthalmic use approved by the U.S. Food and Drug Administration (FDA), is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye), an inflammatory disease that afflicts more than 16 million people in the U.S.[1] CEQUA is the first and only FDA-approved cyclosporine treatment delivered with nanomicellar (NCELL™) technology, which helps to improve the bioavailability and physicochemical stability of cyclosporine, resulting in improved ocular tissue penetration.

"The U.S. launch of CEQUA, the third product in our growing ophthalmic portfolio, marks the availability of a truly innovative treatment option for patients with dry eye disease – an area with a high unmet medical need," said Abhay Gandhi, CEO North America, Sun Pharma. "As a higher concentration cyclosporine product than what is currently commercially available, delivered with NCELL technology, CEQUA continues to demonstrate our leadership in creating novel formulations of proven medications."

This announcement follows the recent publication of results from a multicenter, randomized, double-masked, vehicle-controlled Phase 3 confirmatory study in which 744 patients with dry eye were treated either with CEQUA or its vehicle. After 12 weeks of treatment, as compared to vehicle, CEQUA showed a statistically significant improvement in the primary endpoint, percentage of patients with an increase of at least 10 mm in Schirmer's score (a measurement of tear production) from baseline (16.6% vs. 9.2%; $p<0.01$). Additionally, CEQUA was associated with statistically significant improvements in the key secondary endpoints, with improvements in both corneal and conjunctival staining, compared to vehicle; improvement in total corneal staining was evident as early as one month following treatment, with 65% of eyes having completely clear central cornea after 12 weeks (vs 56.9% for vehicle; $p=0.0022$). Adverse events (AEs) reported in the trial were mostly mild in severity. The most commonly reported ocular AE was instillation site pain (24.2% in

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the CEQUA group, vs. 4.3% for vehicle); of the 24.2% of patients who reported instillation site pain in the CEQUA group, most of them reported the pain as being mild (20.7%), 3.0% reported it as moderate, and 0.5% reported it as severe.

"CEQUA is an important addition to the treatment armamentarium for keratoconjunctivitis sicca, a complex condition that is not conducive to a one-dimensional therapeutic approach," commented Joseph Tauber, M.D., founder, Tauber Eye Center in Kansas City, MO. "The availability of CEQUA will enable eye care professionals to further tailor dry eye treatment to individual patients' needs."

Paul Karpecki, O.D., FAAO, director of cornea services at the Kentucky Eye Institute in Lexington, KY, added, "Keratoconjunctivitis sicca causes symptoms of burning, stinging, itching, grittiness, and dryness, underscoring the need for tolerable drug therapy with a fast onset of action. The CEQUA clinical study results strengthen the rationale for using this product as a means to penetrate the tear film and improve drug delivery of cyclosporine into the eye."

Sun Pharma is also introducing CEQUA SUPPORT™ Specialty Pharmacy, a program designed to enable commercially insured patients to easily obtain CEQUA. Once a patient's prescription is submitted, CEQUA SUPPORT will provide several important services including insurance plan benefits verification, prior authorization support, and appeals assistance. This program is structured to minimize out-of-pocket cost and provides free home delivery.

For more information about CEQUA, CEQUA SUPPORT Specialty Pharmacy and additional prescription processing options, go to Cequa.com or call 1-833-44-Cequa.

About CEQUA

CEQUA (cyclosporine ophthalmic solution) 0.09% is a patented, novel, proprietary nanomicellar (NCELL) formulation of cyclosporine in a clear, preservative-free, aqueous solution. CEQUA provides the highest FDA-approved concentration of cyclosporine for ophthalmic use and is the first and only approved cyclosporine treatment delivered with NCELL technology. The innovative NCELL formulation penetrates the aqueous layer of the tear film in the eye, then the nanomicelles break up to release cyclosporine to penetrate ocular tissues.

CEQUA is dosed twice daily and will be available as a single-use vial. In a multicentered, randomized, double-masked, vehicle-controlled Phase 3 confirmatory study involving 744 patients with dry eye, investigators observed clinically and statistically significant improvements in tear production and ocular surface integrity in patients treated with CEQUA, compared to vehicle. CEQUA treatment was well tolerated in the Phase 3 trial; treatment-emergent adverse events were primarily mild in intensity. In a prior Phase 2b/3 clinical trial with 455 patients, CEQUA demonstrated clinically and

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statistically significant increases in tear production (16.8% of patients with an increase of ≥10 mm in Schirmer's score from baseline after 84 days of treatment, versus 8.6% for vehicle; $p<0.01$) and was well tolerated by the study population. Additionally, several key secondary endpoints showed statistically significant improvements compared to vehicle. From both clinical trials, 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.

Full Prescribing Information & for more information, visit CEQUA.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.[1-2]

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

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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 Ophthalmic

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 addition to CEQUA™ (cyclosporine ophthalmic solution) 0.09%, Sun Ophthalmics markets BromSite® (bromfenac ophthalmic solution) 0.075% and Xelpros™ (latanoprost ophthalmic solution) 0.005% in the U.S. 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 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 & follow us on Twitter @SunPharma_Live

References:

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