

Santen Announces Topline Result from Phase II Clinical Trial of DE-127 for Patients with Mild and Moderate Myopia

December 23, 2019, Osaka, Japan—Santen Pharmaceutical Co., Ltd. (hereinafter, “Santen”) announced that the APPLE Study—a Phase II clinical trial conducted in Asia aimed at assessing the safety and efficacy of DE-127 (generic name: atropine sulfate) in patients with mild and moderate myopia—met its primary endpoint. The primary endpoint of the clinical trial conducted to assess the safety and efficacy of DE-127 was changes in the objective spherical equivalent* after 12 months of drug administration. No severe adverse events were observed throughout the trial period.

DE-127 is a proprietary novel topical formulation developed jointly by Santen and the Singapore Eye Research Institute (SERI), Singapore’s national ophthalmic and visual research institute. Santen has actively promoted collaboration and open innovation with various external organizations in order to enhance the QOL of people around the world through eye health. On November 12, 2014, Santen and SERI initiated multiyear strategic joint research by taking advantage of both parties’ strengths in research and development in the ophthalmic field, with the aim of developing new drugs for eye diseases that often strike people especially in Asia. Santen and SERI will continuously aim to create new products that can contribute to treatment of patients by making the most of both parties’ high level of expertise.

Professor Donald Tan, SERI Senior Scientific Advisor, who served as clinical investigator in the trial, commented as follows: “we were very pleased that our SERI-Santen clinical trial using a new topical formulation of atropine was efficiently and well-conducted, demonstrating that our ongoing industry collaborations with Santen can indeed make a difference to patients globally.”

Phase II/III clinical trials are currently underway in Asia and Japan. Santen plans to apply for approval of manufacturing and marketing in the future.

*corrective power required for vision

About DE-127

DE-127 (generic name: atropine sulfate) is a muscarinic receptor antagonist that suppresses the progression of myopia. Santen has collaborated with the Singapore Eye Research Institute (SERI), Singapore's national ophthalmic and visual research institute, in developing this pipeline pharmaceutical product and carrying out clinical trials for it in Japan and Asia.

About APPLE Study

APPLE Study is a randomized, double-masked, placebo-controlled, parallel-group study aimed at assessing the safety and efficacy of DE-127 in patients aged 6 to 11 with mild or moderate myopia. With the participation of 100 patients in total at two medical institutions in Singapore, 12-month drug administration in the trial was completed in September 2019.

About myopia

After entering the human eye, light is refracted while passing through the cornea and the crystalline lens, resulting in an upside-down image projected on the retina. Myopia denotes a vision condition where unadjusted incoming light focuses in front of the retina. This condition is thought to be mainly caused by the extension of the eyeball from the front to the rear. The degree of myopia is expressed in the spherical equivalent refractive error (unit: diopters [D]). The International Myopia Institute classifies myopia according to the value of the spherical equivalent refractive error, defining the condition of an eye with a spherical equivalent refractive error of ≤ -0.5 D as "myopia" and the condition of an eye with a spherical equivalent refractive error of ≤ -6.0 D as "high myopia." It has been reported that high myopia patients are at high risk of complications that can lead to vision loss.

Myopia is generally corrected by glasses or contact lenses. In addition to these, various treatments that suppress the progression of myopia, including ophthalmic solutions, contact lenses, and orthokeratology, are being developed, and a wide range of clinical trials are being conducted.

About the Singapore Eye Research Institute (SERI)

The Singapore Eye Research Institute (SERI) is Singapore's national research institute for ophthalmic and vision research. It is the research arm of Singapore National Eye Centre, and affiliated to the National University of Singapore (NUS) and the Duke-NUS Medical School. SERI has close working relationships with A*STAR Research Institutes, Nanyang Technological University and other biomedical institutions and eye centers in Singapore and throughout the world. SERI's national mandate drives the organization to constantly explore areas of synergies, and opportunities for multidisciplinary collaborative research partnerships with the various public healthcare eye institutes, and other biomedical research institutions. In this regard, SERI ensures that its expertise, facilities and resources are open to researchers across Singapore so that the greatest benefit may be secured from what is a relatively small clinical ophthalmology catchment area in Singapore.

Since its establishment in 1997, SERI has grown from a founding team of five to a faculty of 220 encompassing clinician scientists, scientists, research fellows, PhD students and supporting staff, with an annual budget of approximately S\$22 million. This makes SERI one of the largest research institutes in Singapore and the largest eye research institute in the Asia-Pacific. In addition, SERI has over 80 adjunct faculties from the various eye departments as well as biomedical institutes and tertiary centres in Singapore. SERI has amassed an impressive array of publications amounting to more than 3,700 scientific papers as of September 2019, and has secured more than 340 external peer-reviewed competitive grants worth \$327 million. SERI's faculty has been awarded with more than 610 national and international prizes and filed more than 130 patents. SERI has further contributed to research manpower training, including 204 Masters, PhD and post-doctoral students, many of whom are now working in hospitals, biomedical sciences industry, academic institutions and A*STAR institutes. As a non-profit entity that is heavily reliant on competitive grants as the main source of funding, SERI has always adopted a lean and optimal approach in fund utilization via leveraging on shared resources to support our research projects.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan, and its products now reach patients in more than 60 countries. With scientific knowledge and organizational capabilities nurtured over a nearly 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website (www.santen.com).

Santen Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

Contact

Corporate Communications Group, Santen Pharmaceutical Co., Ltd.

+81-6-4802-9360, ir@santen.com