



Santen and Sydnexis execute an exclusive licensing agreement for SYD-101, a novel investigational treatment for progressive childhood myopia

10 August 2021 – Geneva, Switzerland – Santen SA, a specialist in ophthalmology, and Sydnexis Inc., a biopharmaceutical company focused on the development of therapies for the treatment of progressive myopia, announce the signing of an exclusive licensing agreement for SYD-101, Sydnexis' investigational proprietary low dose atropine formulation, for Europe, Middle East and Africa (EMEA). SYD-101 is currently undergoing a large multicenter phase III clinical trial, the STAAR study, in Europe and the US. If the study is successful and SYD-101 is thereafter approved, it will address the need for a medical product to help control myopia progression.

“Uncorrected myopia is the leading cause of distance vision impairment and it is children with early onset who are at greater risk of long-term eye complications,” says Dr Martina Brandner, Department of Ophthalmology, Medical University of Graz, Austria. “At present, only the symptoms of myopia are corrected and so researching SYD-101 in the largest clinical study in this field is a critical step in finding a treatment to target the underlying disease.”

SYD-101 is an investigational low-dose atropine sulfate ophthalmic solution, 0.01% and 0.03%, designed to achieve efficacy, stability and reduce discomfort for improved treatment continuity.^{1,2} While published reports have shown low concentrations of compounded atropine to be effective, these solutions are limited by a short shelf life and remain only stable if markedly acidified, which can also cause excessive burning and stinging in children.^{3,4} Based on its unique and proprietary formulation, SYD-101 is an investigational low-dose atropine formulation designed to be pharmacologically stable without needing to lower the pH in order to achieve a shelf life of up to three years at room temperature.⁵

“We are excited to partner with Santen, a global leader in ophthalmology to help fulfill our goal of making SYD-101 available in EMEA. We recognise the expertise that Santen brings to the table in understanding and navigating the registration process in the EMEA region and look forward to collaborating with Santen in addressing the myopia needs in these broader geographic regions,” states Kenneth Widder, CEO of Sydnexis. “Myopia is a global epidemic that has only been exacerbated with the increased computer screen-time during the COVID lock-down.”

As one of the most common ocular disorders, myopia is a growing public health challenge projected to affect 5 billion people globally by 2050.⁶⁻⁸ In Europe alone, the prevalence of myopia is estimated to

increase to almost 42% by the end of this decade.⁸ The growing incidence and severity of the condition are largely attributed to lifestyle changes as children are spending more time on near-vision activities (reading, studying and using digital devices) and less time outdoors.^{6,9} In the absence of treatment, high or fast-progressing myopia can lead to serious eye health concerns such as glaucoma, cataract and retinal detachment later in life that can cause irreversible vision loss.⁸ Currently, childhood myopia in Europe is corrected with prescription glasses or contact lenses, which do not slow its progression. In response to the rising number of cases, the European Society of Ophthalmology has issued guidance advocating for the inclusion of atropine treatment as well as promoting increased outdoor time.⁹

“Children’s eye health is an important part of their overall health and influences their development and so Santen is proud to be partnering with Sydnexis. As part of this agreement, we will work together to bring SYD-101 to the market in EMEA as potentially a significant tool to slow the progression of myopia,” says Luis Iglesias, President and Head of Santen EMEA. “Without treatment, the long-term complications associated with myopia continue to impair patients’ lives well into adulthood. Through this collaboration, we will also continue to learn from patient experiences so we can apply our combined expertise and tackle the growing burden of this childhood eye condition.”

“On July 23, the United Nations General Assembly adopted the first ever resolution on eye health with the linkage between eye health and Sustainable Development Goals. This announcement represents a major leap to reduce the loss of social and economic opportunities for people around the world due to eye health conditions,” said Shigeo Taniuchi, President & CEO of Santen. “We see myopia as a growing social issue and we firmly commit to tackle this disorder for serving patients’ unmet needs as a specialised ophthalmology company. It will also become a growth driver in our mid-to-long-term business. By adding SYD-101 to our existing pipeline, this partnership can enable us to build our business foundations globally in an efficient manner to serve myopia patients in need.”

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References

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About myopia

After entering the human eye, light is refracted while passing through the cornea and the crystalline lens onto 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 abnormal elongation 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 as myopia increases in patients so do the risks 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 STAAR study

The STAAR study is a global multi-center, randomized, double masked, placebo-controlled trial evaluating two dosage strengths of SYD-101 in more than 850 children between the ages of 3-14. The study will measure myopia progression between experimental and control arms using a number of endpoints including the proportion of patients progressing by a certain amount of spherical equivalent (SE), the average progression rate as measured by SE, and the average increase in axial length.

About Sydnexis Inc.

Sydnexis Inc. is a venture backed, clinical stage ophthalmic biopharmaceutical company focusing on its patent protected formulation of low dose atropine to enhance the lives and improve myopic progression in children with progressive myopia.

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, and its products now reach patients in over 60 countries.

Toward realizing “WORLD VISION” (Happiness with Vision), the world Santen ultimately aspires to achieve, as a “Social Innovator”, we aim to reduce the social and economic opportunity loss of people around the world caused by eye diseases and defects by orchestrating and mobilizing key technologies and players around the world.

With scientific knowledge and organizational capabilities nurtured over a 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).

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