Santen and ActualEyes start registering patients to participate in Phase II clinical trial (Phase IIa / PoC study, PHANTOM study) for Fuchs endothelial corneal dystrophy

May 31, 2022, - Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; hereinafter “Santen”) and ActualEyes Inc. (Kyotanabe, Kyoto; hereinafter “ActualEyes”) are pleased to announce that the first patient was registered in the United States on May 19, 2022 (Pacific Standard Time) in Phase II clinical trial (Phase IIa / Proof of Concept study, PHANTOM study) for the global development of sirolimus eye drops (Santen development code “STN1010904” and ActualEyes development code “AE-001”) for treating Fuchs endothelial corneal dystrophy (FECD).

FECD is a corneal disease, which is said to affect approx. 4% of people aged 40 or over in Europe and the United States[1]. When it progresses, FECD causes corneal opacity and corneal edema, which reduce vision and result in a condition called bullous keratopathy, thereby significantly undermining patients’ quality of life (QOL). Corneal transplant, using a donor cornea, is the only treatment option currently available[2]. In fact, treating this condition accounts for about 40% (highest ratio) of corneal transplant surgeries performed globally[3]. At the same time, corneal transplant involves a variety of issues including global donor shortages, cornea rejection and invasive nature of the surgery. Hence, there is a strong need for a new treatment option in the form of eye drops, which reduce the burden on patients.

“FECD is a disease that causes photophobia in the early stages, and significant vision loss and severe pain in the middle to late stages leading to blindness,” says Reza Haque, the Head of Ophthalmology Innovation Center, Santen. “By leveraging Santen's capabilities in global R&D, and ActualEyes's strengths in research findings from pathological analysis and drug screening, and its extensive network in the ophthalmological community, we are committed to accelerate the development of innovative therapeutics to protect patients from the risk of future vision loss.”

“FECD is a disease that has no treatment option to halt its progression and corneal transplantation is currently the only treatment available,” says Naoki Okumura, Director of ActualEyes, ophthalmologist and professor of Doshisha University’s Department of Biomedical Engineering. “Sirolimus eye drops have the potential of becoming the world’s first therapeutic for treating FECD. This eye drop could become an epoch-making option for treating FECD patients, many of whom suffer from poor vision. We are hoping that the initiation of this Phase II clinical trial will be the first step in bringing a new treatment option to patients with FECD.”

The two companies will work diligently toward launch of STN1010904/AE-001 to contribute to the treatment of patients suffering from FECD and to improving their QOL.

See the press release issued on November 18, 2021 about the joint development agreement the companies signed for this project. (https://www.santen.com/en/news/20211118-2.pdf)

*The development code (STN1010904) is due to be assigned to the product when Santen obtains exclusive license upon completion of Phase II clinical trial

[Reference]

1. Moshirfar M et al. Fuchs Endothelial Dystrophy. Treasure Island (FL):StatPearls Publishing;2021.
2. Okumura N et al. Perspective of Future Potent Therapies for Fuchs Endothelial Corneal Dystrophy. Open Ophthalmol J. 2018;12:154-163.
3. Gain P et al. Global Survey of Corneal Transplantation and Eye Banking. JAMA Ophthalmol. 2016;134(2):167-173.

About Phase II clinical trial for STN1010904 / AE-001 (Phase II a / PoC study, PHANTOM study)

This trial, conducted on approx. 80 FECD patients aged 30 – 75, is a joint international multi-center, double-blind, randomized placebo-controlled trial in the United States, France, and India, exploring the efficacy and safety of STN1010904 / AE-001 at two concentrations. It tests best-corrected visual acuity, best-corrected low-contrast visual acuity and contrast sensitivity to study the agent's efficacy and safety in treating FECD. For more information, please refer to www.clinicaltrials.gov (NCT05376176).

About ActualEyes

ActualEyes is a bio-venture company that was established based on novel researches by Noriko Koizumi, M.D., Ph.D. and Naoki Okumura, M.D., Ph.D. (Ophthalmologists and Professors of Doshisha University). ActualEyes is committed to research and development of both pharmacological treatments for FECD and the cell therapy for corneal endothelial dysfunction.
For more information, please visit ActualEyes' website (www.actualeyes.co.jp/en/)

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 and regions.

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 (https://www.santen.com/en/).

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