



**Santen and ActualEyes sign a joint development agreement on
Phase II clinical trial (Phase II a / PoC study)
for a treatment candidate for Fuchs endothelial corneal dystrophy**

November 18, 2021, Osaka, Japan- Santen Pharmaceutical Co., Ltd. (hereinafter “Santen”) and ActualEyes Inc. (Kyotanabe, Kyoto, hereinafter “ActualEyes”) have signed a joint development agreement on Phase II clinical trial (Phase II a / Proof of Concept study) toward global development for 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, said to affect approx. 4% of people aged 40 or over in Europe and the United States¹. When it progresses, FECD causes corneal opacity and corneal edema, which reduce vision and result in a condition called bullous keratopathy, significantly undermining patients’ quality of life (QOL). Corneal transplant, using a donor cornea, is the only treatment option currently available². In fact, about 40% (largest percentage) of corneal transplantation performed globally is for treating this condition³. 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 impose reduced burden on patients.

The agreement stipulates the roles and responsibilities of Santen and ActualEyes in the joint development, as well as Santen's exclusive right to negotiate and basic terms and conditions at negotiation (e.g., upfront, milestone, royalty, etc.) for global exclusive licensing at the time of completion of the Phase II clinical trial.

Both companies will undertake development work toward early market introduction of the STN1010904 / AE-001 as a FECD treatment, with the aim of contributing to the treatment of FECD patients and the improvement of their QOL.

*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)

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.

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)

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).

Contact

Corporate Communications Group

Santen Pharmaceutical Co., Ltd.

E-mail: communication@santen.com

ActualEyes Inc.

Masahiko Kato, Senior Director, General Administration

E-mail : masahiko.kato@actualeyes.co.jp