

Announcement of the Completions of Final Observations in the Domestic Phase II Clinical Trial of the Regenerative Medicine Cell Product AE101 and the Start of Preparation for the Phase III Clinical Trial

We and D-Western Therapeutic Institute, Inc (DWTI) are pleased to announce you that we have completed the final observation for all subjects in the domestic phase II clinical trial of our regenerative medicine cell product AE101.

This study aims to investigate the safety and efficacy of AE101 transplantation in patients with bullous keratopathy. In the future, all data will be collected and analyzed.

Currently, in terms of safety, no serious adverse events that cannot exclude a causal relationship with the investigational product have been observed, and in terms of efficacy, an improvement in visual acuity has been suggest.

We will continue to advance data analysis and prepare to start the Phase III clinical trial within the 2026.

Comment from Dr. Naoki Okumura, the medical expert for this clinical trial (our founder and director)

"We are delighted to announce the successful conclusion of our one-year follow-up study for all participants who underwent exploratory corneal regenerative cell-based therapy. This achievement represents a significant milestone in the clinical development of our innovative treatment approach. Drawing from insights gained through this exploratory study, we have made substantial refinements to the clinical trial protocol. These enhancements are designed to rigorously evaluate both the efficacy and safety profile of our therapy. We remain fully committed to adhering to the highest standards of scientific integrity and ethical responsibility throughout the implementation process, in close collaboration with our partner institutions."

AE101 is a cryopreserved formulation of cultured human corneal endothelial cells, where human corneal endothelial cells are expanded in vitro and suspended in a cryoprotectant solution containing a Rho kinase inhibitor. The product is injected into the anterior chamber of the eye to promote regeneration of the corneal endothelium.

To expedite the availability of AE101 as a treatment for patients, ActualEyes and DWTI will continue to advance this clinical trial, focusing on confirming both its efficacy and safety.

Terminology

*1 Bullous keratopathy

A condition in which the corneal endothelial cells are damaged, leading to corneal edema, whitening, and cloudiness, resulting in significant vision loss. Causes include Fuchs endothelial corneal dystrophy, cataract surgery, glaucoma, and other ocular surgeries that damage the corneal endothelial cells. The current treatment is corneal transplant surgery using donor corneas.