

**Aiming at Early Commercialization of Regenerative Medicine for Corneal Endothelium  
Manufacturing of regenerative medical product candidate AE101 starting at J-TEC.**

ActualEyes Inc. (Kyoto, Japan; President & CEO; Iku Sugioka, hereinafter "ActualEyes") started manufacturing of a regenerative medical product candidate for the treatment of corneal endothelial diseases (development name: AE101), which is jointly developed with D. Western Therapeutics Institute, Inc. (Aichi, Japan; President & CEO, Yuichi Hidaka), at Japan Tissue Engineering Co., Ltd. (Headquarters in Gamagori, Aichi, Japan; President & CEO, Ken-ichiro Hata, hereinafter "J-TEC"). We will promote the development of AE101 and aim at early commercialization of regenerative medicine for corneal endothelium by outsourcing the manufacturing to J-TEC which has an extensive track record in the development, manufacturing, and sales of regenerative medical products.

We are a bioventure company originated from Doshisha University where new ophthalmic treatment is being developed such as regenerative medicine for overall corneal endothelial diseases and drug therapy for Fuchs endothelial corneal dystrophy. Corneal endothelium is indispensable to maintain the transparency of the cornea. If the corneal endothelium is damaged, the cornea becomes cloudy and vision is severely impaired. Corneal endothelial damage accounts for more than half of the causes of corneal transplantation, and corneal transplantation due to corneal endothelial damage has been increasing every year. Meanwhile, there is a global shortage of donors, and a novel solution is desired. We have developed a regenerative medical product candidate AE101 which is a mixture of corneal endothelial cells cultured from the donor cornea and ROCK (Rho-associated kinase) inhibitor and aim at resolving the shortage of donors and achieving early commercialization of regenerative medicine for corneal endothelium.

#### About corneal endothelial impairment

Corneal endothelium is positioned on the inside of the cornea (inside the eye) and is indispensable to keeping the cornea transparency. It does not regenerate in the living body. If it is damaged by diseases, eye surgery, etc., the cornea loses its transparency and becomes cloudy, which leads to severe visual impairment. At present, the only treatment is corneal transplantation in which a cornea provided by a deceased donor is transplanted. However, there are problems worldwide such as lack of donors, graft failure, rejection, and difficulty in surgery. While corneal transplantation is an essential treatment, it is actually quite a burden on patients and ophthalmologists.

**About ActualEyes Inc.** (headquartered in Kyotanabe, Kyoto Prefecture)

Founded based on the research of Noriko Koizumi, M.D., Ph.D. and Naoki Okumura, M.D., Ph.D. (ophthalmologists and professors at Doshisha University's Department of Biomedical Engineering), ActualEyes is engaged in research and development into both regenerative medicines and pharmacological treatments for FECD and other forms of corneal endothelial dysfunction. For more information, please visit ActualEyes' website ([www.actualeyes.co.jp/en/](http://www.actualeyes.co.jp/en/)).

**About Japan Tissue Engineering Co., Ltd. (J-TEC)**

J-TEC is a manufacturer of regenerative medical products with the corporate vision "Creating a future for regenerative medicine," and currently manufactures and distributes four regenerative medicine products including autologous cultured epidermis "JACE®", Japan's first regenerative medical product. In addition to the regenerative medical product business (development, manufacturing, and marketing of regenerative medicine products in Japan), J-TEC is engaged in the contract business of regenerative medicine (CDMO/CRO services related to regenerative medicine) and research and development support business (development, manufacturing, and marketing of human cultured tissues for research). Please visit J-TEC website [www.jp-tec.co.jp](http://www.jp-tec.co.jp) for more information.

**About D. Western Therapeutics Research Institute, Inc.** (headquartered in Nagoya, Aichi Prefecture)

Based on the vision of bringing "Innovative New Drugs to the World from Japan," D. Western Therapeutics Institute (DWTI) is a bioventure aiming to deliver more effective new drugs as soon as possible to the patients who need them. DWTI's strength is in the discovery of kinase inhibitors, some of which already have been brought to market. Currently, DWTI is focusing on the field of ophthalmology, to aid in selection of the optimal treatment for each patient. For more information, please visit DWTI's website ([www.dwti.co.jp/english/](http://www.dwti.co.jp/english/)).

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