

Concluded a capital tie-up and joint development agreement for regenerative medicine cell-therapy products for corneal endothelial disorders

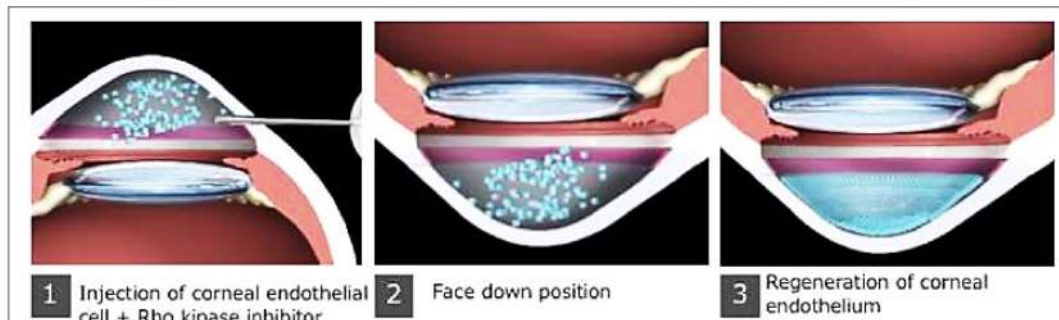
SUMMARY

- ✿ DWTI announced at 15:30 on Thursday June 30, 2022 that it has concluded a capital tie-up and joint development agreement with ActualEyes Inc. (President & CEO Iku Sugioka, head office Kyotanabe-city, Kyoto) for joint development in Japan of regenerative medicine cell-therapy product candidate AE101 for treatment of corneal endothelial decompensation. **So far in DWTI's development pipeline, there have been six license out products, and eight clinical development products.**
- ✿ AE-101 is a novel cell injection therapy developed by ActualEyes as a regenerative cell therapy for the indication of bullous keratopathy, which is an eye disorder that involves a blister-like swelling of the cornea (the clear layer in front of the iris and pupil), using cultured human corneal endothelial cells (hCECs) combined with a Rho-associated kinase (ROCK) inhibitor (see exhibit below). With the conclusion of this agreement, DWTI's development code for this drug will be "DWR-2206."
- ✿ All proceeds from DWR-2206 will be split between ActualEyes and DWTI (this includes milestone and royalty payments from China bio-venture Artic Vision, to which ActualEyes has already licensed out), and the two companies plan to proceed with clinical trials in Japan with the aim of obtaining manufacturing and marketing approval as soon as possible. Although there is no upfront payment associated with this agreement, DWTI as one of two investors will underwrite 130 million yen of the 330 million yen third-party allotment of shares issued by ActualEyes, for an ownership ratio of 7.0% of total shares outstanding. DWTI's Board of Directors resolved to borrow funds for the development of DWR-2206 through the conclusion

Regenerative Medicine: new technology for the treatment/prevention of disease

Cells are obtained from the human body and cultured, or cultured and otherwise processed, to repair, regenerate and restore certain tissue or organ functions that have been lost due to causes such as illness, accidents, or aging.

Cell-Therapy Product AE101 for Treatment of Corneal Endothelial Decompensation



Source: ActualEyes Inc. website. <https://www.actualeyes.co.jp/technology/>

News Flash



D. WESTERN THERAPEUTICS INSTITUTE

Focus Points:

Drug discovery bio-venture with strengths in the kinase inhibitor mechanism and treatments for ophthalmic diseases such as glaucoma and ocular hypertension.



Business Objectives:

Doshisha University venture company established for the development and launch of two specific products: 1) eye drops for the treatment of Fuchs endothelial corneal dystrophy (FECD) and 2) a cell-therapy product for treatment of corneal endothelial decompensation.



Description:

China-based ophthalmic biotech focusing on breakthrough therapies, with a leading portfolio covering pre-clinical stage to commercial stage products.

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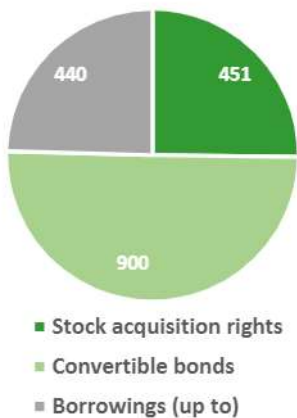


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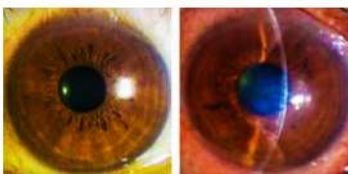


PIPELINE EXPANSION

JPY 1,791mn Fund-Raising Summary



Normal cornea (left), Fuchs' corneal endothelial dystrophy (right)



Source: ActualEyes website.

Continued from P1

of a line of credit agreement with Mizuho Bank, Ltd. (borrowing limit up to 440 million yen). Funds for development and this investment will come from fund-raising and borrowing. In a separate announcement at the same time, DWTI announced details of its new fund-raising through issuance of the 1st unsecured convertible bonds with stock acquisition rights and the 11th stock acquisition rights by third-party allotment. **This is a significant new development for DWTI, and it is not included in its MTP announced February 10, 2022.**

- ✳ Terms and specifications of the 1st unsecured convertible bonds with stock acquisition rights include: 1) total fund-raising amount: 900 million yen, 2) payment date: July 19, 2022, 3) number of stock acquisition rights units: 49, 4) issue price of each bond is 18,367,347 yen (100 yen per par value of 100 yen), the issue price of the stock acquisition rights attached to the bonds is gratis, 5) potential dilution from this issue is 4,864,864 shares (roughly 16.53% of shares outstanding), 6) conversion price: 185 yen, 7) the entire amount will be allocated to Whiz AIoT Evolution Fund Investment LP, and 8) the bonds do not bear interest, and the redemption date is December 27, 2027.
- ✳ Terms and specifications of the 11th stock acquisition rights by third-party allotment include: 1) total fund-raising amount: 451.2 million yen, 2) allotment date: July 19, 2022, 3) number of stock acquisition rights units: 24,324, 4) issue price: 1.2 million yen (50 yen per SAR unit), 5) potential dilution from this issue is 2,432,400 shares (100 shares per SAR unit, roughly 8.26% of shares outstanding), 6) exercise price: 185 yen, 7) through third-party allotment, all stock acquisition rights will be allocated to Whiz AIoT Evolution Fund Investment LP, and 8) exercise period: from July 19, 2022 through December 24, 2027.
- ✳ Three reasons for DWTI becoming involved with regenerative medicine cell-therapy products for corneal endothelial disorders: i) **Ophthalmology Field:** enhances DWTI's focus on ophthalmologic diseases, ii) **Corneal Endothelial Disorders:** caused by a variety of factors, **the only treatment is corneal transplant surgery, and there is no cure**, and, **unmet medical needs are high due to the global shortage of donors, graft failure, and difficulty of the surgical procedure**, and iii) **Regenerative Medicine:** new treatment technology that can fulfill unmet medical needs, and the acquisition of new modalities can contribute to patients' optimal treatment choices.
- ✳ According to data from the Ministry of Health, Labour and Welfare, there are an estimated 7,000-10,000 patients in Japan with bullous keratopathy. According to research by DWTI, the number of corneal transplants is said to be about 3,000, with a waiting list of 10,000 to 20,000. Also, only 1 in 70 patients worldwide who need a corneal transplant can undergo the surgery. In the US, the estimated number of patients with Fuchs' corneal endothelial dystrophy (FCED) is approximately 6 million (DWTI). The incidence rate in people over 40 years old in the US and Europe is roughly 4% (ActualEyes). The estimated number of patients in China with corneal endothelial disorder is over 1 million (DWTI).
- ✳ Bullous keratopathy is a late stage of various corneal endothelial disorders, including Fuchs' corneal endothelial dystrophy (FCED), so the number of potential patients is large. As for regenerative medicine cell-therapy products, products for corneal epithelial disorders are leading development. There are also expectations to launch products for corneal endothelium as a result of technological innovation.

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