

Arctic Vision announces exclusive licensing agreement with ActualEyes to develop and commercialize cell therapy to potentially replace corneal endothelial keratoplasty in Greater China and South Korea

- Arctic Vision to partner with ActualEyes to introduce novel approach of using cultured corneal endothelial cells to treat corneal endothelial dysfunction and potentially replace corneal endothelial keratoplasty.
- Under the terms of the agreement, the deal is worth up to more than USD 35 million, including upfront, regulatory milestone payments, and tiered royalties.



Shanghai, CHINA and Kyoto, JAPAN, May 14, 2021 /PRNewswire/ -- Arctic Vision, a clinical stage biotech company focused on innovative ophthalmology therapies for pan-ocular diseases, and ActualEyes, a clinical stage Japanese biotech company committed to the research and development of cell therapy for corneal endothelial diseases, today jointly announced an exclusive licensing agreement for Arctic Vision to develop and commercialize ActualEyes' lead product candidate, AE-101, for the treatment of corneal endothelial dysfunction in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea.

Under the terms of the agreement, ActualEyes may receive up to more than USD 35 million payments, including upfront payment, future regulatory milestones, and tiered royalties on net sales.

Corneal endothelial dysfunction is the result of severe endothelium damage caused by different pathologies, including Fuchs' endothelial corneal dystrophy (FECD), pseudophakic bullous keratopathy, trauma, glaucoma, and endothelial keratitis, etc. It is estimated that over one million patients suffer from corneal endothelial dysfunction in China, and in the most severe cases, the most effective treatment is corneal keratoplasty (penetrating keratoplasty and endothelial keratoplasty). However, due to a severe shortage of donor corneas, less than ten percent of these patients in China may receive a keratoplasty. At the same time, keratoplasty may have associated problems, such as potential graft failure, infection, implant drop and unpredictable refractive state. Moreover, the keratoplasty operation itself is demanding and technically challenging for surgeons.

AE-101 is a novel cell-injection therapy developed using cultured human corneal endothelial cells (hCECs) combined with a Rho-associated kinase (ROCK) inhibitor. Studies^{i,ii} have demonstrated that the injection of hCECs supplemented with a ROCK inhibitor has strong efficacy and safety profiles in patients with corneal endothelial dysfunction. The ground-breaking clinical research findings published in the *New England Journal of Medicine* and *Ophthalmology* led by ActualEyes' scientific founders, Dr. Noriko Koizumi and Dr. Naoki Okumura, have shown that AE-101 can effectively restore corneal endothelial function as well as vision, with no major treatment-relevant adverse reactions for up to 5-years post-operation, which represents a paradigm shift in corneal regenerative medicine.

Dr. Eddy (Hoi Ti) Wu, Founder and CEO, Board Director of Arctic Vision, commented, "We are excited to enter into this partnership with ActualEyes to further develop AE-101, a potent cell-therapy solution for the treatment of corneal endothelial dysfunction. China is a market with high prevalence of corneal diseases as well as huge unmet clinical need due to the shortage of donor corneas. The market potential is tremendous for more accessible therapies with greater safety and efficacy. The licensing of AE-101 represents not only a corporate milestone of incorporating the first cell therapy in our

pipeline, but also our commitment to an overall portfolio strategy aimed to discover and deliver breakthrough therapies for patients in China and Asia.”

Iku Sugioka, President and Chief Executive Officer of ActualEyes, said, “We look forward to collaborating with Arctic Vision to develop our lead clinical candidate AE-101. The potential benefits of cell therapy are significant for patients suffering from vision impairment or loss caused by corneal endothelial dysfunction. From our previous research, AE-101 has great potential to provide a less invasive and more effective therapeutic modality compared to conventional surgical therapies. With the compelling track records of Arctic Vision’s management team in research and commercial fronts, we are confident that this partnership is the start of a long-term relationship to bring our novel AE-101 therapy to broader markets in Asia.”

About ActualEyes

Founded based on the research of Professors Noriko Koizumi and Naoki Okumura at Doshisha University in Kyoto, Japan, ActualEyes is a Japan-based clinical stage biotech company committed to the research and development of both cell therapy and pharmacological treatments for corneal endothelial dysfunction, including Fuchs endothelial corneal dystrophy (FECD) and bullous keratopathy. For more information, please visit www.actualeyes.co.jp

About Arctic Vision

Arctic Vision is a China-based clinical stage specialty ophthalmology company with a leading portfolio of breakthrough technologies. The company’s vision is to address ophthalmology’s unmet needs through innovative therapies in China, Asia and globally. Arctic Vision was established by top-tier life sciences investors and is led by an elite team of ophthalmic industry veterans with substantial and compelling China and global experiences in both R&D and the commercialization of eye care products. For more information, please visit www.arcticvision.com.

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ⁱ Kinoshita, Shigeru & Koizumi, Noriko et al. (2018). Injection of Cultured Cells with a ROCK Inhibitor for Bullous Keratopathy. The New England journal of medicine. 378. 995-1003. 10.1056/NEJMoa1712770.

ⁱⁱ Numa, Kohsaku & Imai, Kojiro et al. (2020). Five-Year Follow-up of First Eleven Cases Undergoing Injection of Cultured Corneal Endothelial Cells for Corneal Endothelial Failure. Ophthalmology. 128. 10.1016/j.ophtha.2020.09.002.