



News Release

Astellas Pharma Inc.
CLINO Corporation

Astellas and CLINO Announce License Agreement to Develop and Commercialize Gene Therapy to Treat Retinitis Pigmentosa

Tokyo and Miyagi, February 1st, 2016 - Astellas Pharma Inc. (TSE : 4503, President and CEO : Yoshihiko Hatanaka, “Astellas”) and CLINO Corporation (President : Noriaki Satake, “CLINO”) today announced that Astellas and CLINO have entered into a license agreement for the worldwide development and commercialization of a gene therapy^{*1)}, Adeno-associated Virus-modified Volvox channelrhodopsin-1 (AAV-mVChR1)^{*2)} to treat retinitis pigmentosa.

Retinitis pigmentosa is an inherited retinal degenerative disease characterized by progressive decreases in night vision, visual field, and visual acuity leading to loss of color vision and blindness. The pathophysiological mechanisms of this retinal degeneration are still not fully understood and treatments with clear clinical efficacies have yet to be established.

Modified Volvox channelrhodopsin-1 (mVChR1), which was invented by Professor Hiroshi Tomita, currently on the Faculty of Engineering in Iwate University, and his colleagues, is an engineered photoreceptive ion channel with the ability to respond to broad wavelengths of lights, created by modifying channelrhodopsins^{*3)} found in green algae. It has been shown that administration of AAV-mVChR1 in a rat model of retinitis pigmentosa results in expression of mVChR1 in retinal ganglion cells and recovery of light sensitivity of those rats, providing a possibility that AAV-mVChR1 may restore visual functions in patients with retinitis pigmentosa.

“We are pleased to enter into this agreement with CLINO whose breakthrough technology has high potential to advance this innovative therapy,” said Kenji Yasukawa, Ph.D., Chief Strategy Officer, Astellas. “We expect to provide this innovative therapy to ophthalmic diseases with unmet medical needs through this collaboration to develop AAV-mVChR1, and to make further contributions to the treatment of patients. This collaboration is crucial for our strategy in ophthalmology where Astellas is actively engaged. We will continue to invest management resources in this field.”

Mr. Noriaki Satake, President of CLINO, commented, “By collaborating with Astellas, we will forge ahead with the development of the innovative technology, launched by Tohoku, in order to contribute to recovery of patients’ vision as soon as possible. We will be grateful if our future achievements could deliver some help to the earthquake disaster reconstruction.”

*1)Gene therapy: a therapy to administer genes or cells introduced with genes into a patient’s body.

*2)AAV-mVChR1 (Adeno-associated Virus-modified Volvox channelrhodopsin-1): Adeno-associated virus vector ^{*4)} carrying modified VChR1 gene.

*3)Channelrhodopsin: A protein that permeates ions in and out of cells in response to photo stimulations.

*4)Adeno-associated virus vector: A small non-pathogenic virus that packages a single-stranded DNA. In gene therapies, it is often used as a carrier (vector) to express therapeutic genes in human bodies

About Astellas

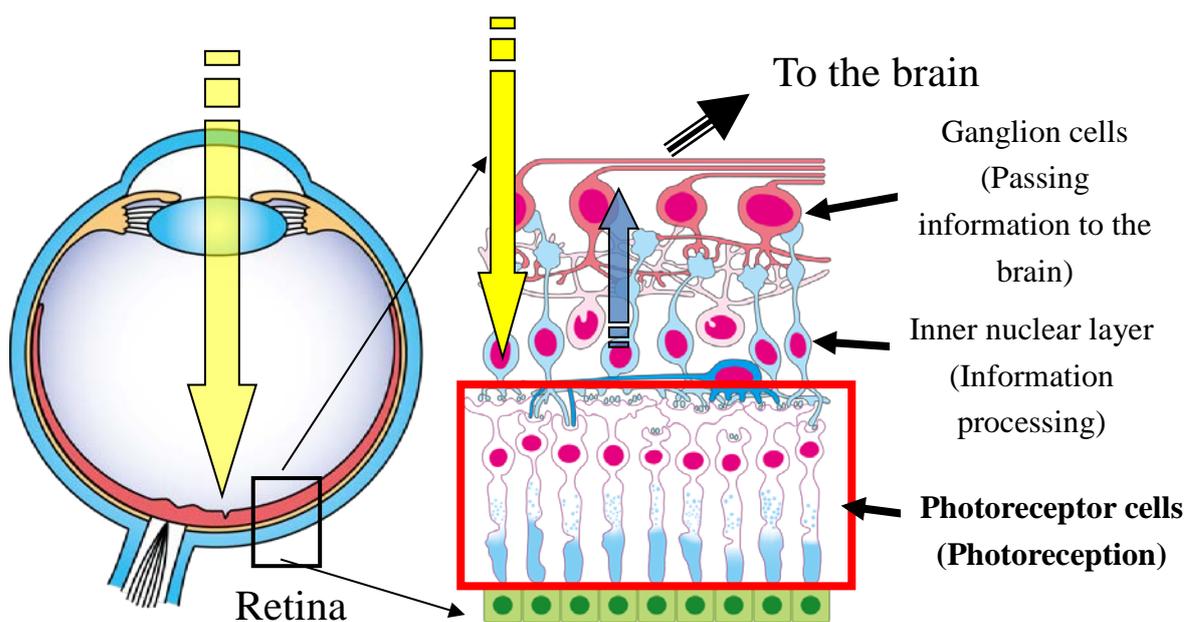
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

About CLINO

CLINO Corporation has advanced its corporate philosophy of contribution to the aging society with fewer children through clinical innovation on the basis of the scientific achievements of Tohoku University Biomedical Engineering Research Organization (TUBERO) and has been engaged in the activity to promote commercialization of innovative seeds. TUBERO was established as a part of the Super Center of Excellence (COE) program sponsored by the Ministry of Education, Culture, Sports, Science and Technology in 2003 and closed in March 2008.

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Photoreceptive mechanism of the retina Images (lights) which enter into eyes are captured by photosensitive cells (photoreceptor cells) located at the outer layer of the retina. While the photoreceptor cells release neurotransmitters in the dark, they reduce the release of neurotransmitters in response to lights. Neurons in inner nuclear layers respond to an increase or decrease in neurotransmitters and transmit signals to ganglion cells. Ganglion cells then transmit the signals to the brain where the signals are perceived as visual information. When photoreceptor cells are impaired or degenerated by some causes, retinas cannot process lights even if other retinal neurons function normally, and vision is lost.

mVChR1 gene

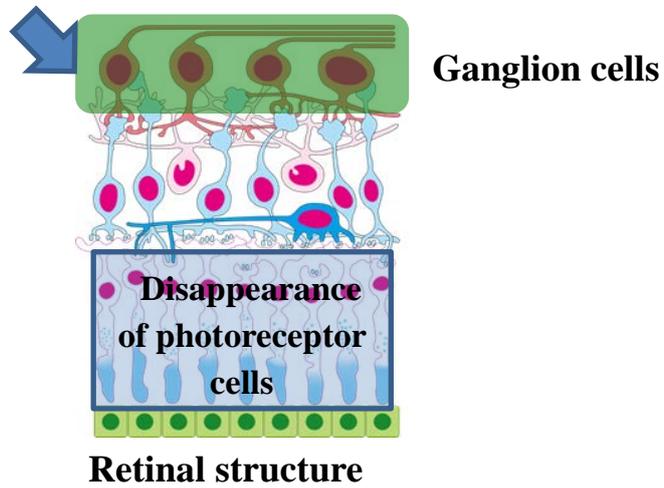


Illustration of treatment

It is expected that, by injecting AAV-mVChR1 into eyes, a gene coding mVChR1 is delivered into ganglion cells that connect the eye and the brain; ganglion cells become photosensitive by expressing mVChR1, and the ability to perceive lights is restored in the absence of endogenous photoreceptor cells.