

## Healios establishes proprietary universal donor cell research line

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Healios K.K., Japan's leading clinical-stage biotechnology company, has been creating Universal Donor Cells (UDCs), which are next-generation iPS cells created with gene-editing technology to engineer a low risk of immune rejection regardless of HLA types. The company is pleased to announce that it has successfully established a proprietary UDC research line and characterized its gene expression and other features.

Healios plans to combine its UDC technology with its existing efforts in next-generation cancer-targeting immune cells, ophthalmology, organ buds and so on to create a line of regenerative medicine therapies with the highest possible safety and efficacy profile.

Typically, transplanted cells trigger an immune rejection response in patients whose HLA type does not match that of the cells. Therefore, doctors must administer an immunosuppressant drug during transplantation, which increases the burden on the patient's body. To avoid the administration of immunosuppressants, it is preferable to utilize autologous iPS cells produced by the patient's own cells, but the production process both takes a long time and is very expensive.

UDCs are iPS cells created using gene-editing technology that allows them to reduce the body's immune rejection response. The production of Healios' UDCs involves the removal of certain HLA genes that elicit a rejection response, the introduction of an immunosuppression gene to improve immune evasion, and the addition of a suicide gene serving as a safety mechanism, each in an allogeneic iPS cell.

This next-generation technology platform allows for the creation of regenerative pharmaceutical products with enhanced safety and a lower risk of immune rejection, while preserving the inherent ability of iPS cells to replicate themselves continuously and their pluripotency in differentiating into various other kinds of cells.

Plans are underway at Healios to promote the internal development of regenerative pharmaceutical products that utilize UDCs and further reinforce the Company's pipeline. It is committed to working towards the early completion of a clinical-grade UDC line that meets global approvability standards.