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(TSE Growth Code: 4593)  
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## **Healios NA Awarded \$1 Million from the California Institute for Regenerative Medicine for Healios' Hypo-immune UDC**

HEALIOS K.K. (“Healios”) is pleased to announce that the California Institute for Regenerative Medicine (CIRM) has awarded Healios NA, Inc. (“Healios NA”), its California, U.S. based subsidiary, an approximately \$1 million Translational Stage 4 (TRAN4) grant in support of its hypo-immune iPSC cells (“Universal Donor Cells” or “UDC”). This funding will enable Healios NA to advance research and development toward a next generation UDC.

Healios is a pioneer in the development of regenerative medicines and is advancing efforts to create new therapeutic medicines using iPSC and other cell lines. Over its greater than a decade of developing iPSC products, Healios has built a suite of proprietary technologies that includes high quality, clinical grade iPSC cell lines. As [announced in October 2020](#), Healios completed the generation of a clinical-grade UDC iPSC line as a next-generation technology platform for the creation of regenerative medicine products with enhanced efficacy and safety by suppressing immune rejection, while maintaining the inherent characteristics of iPSCs such as unlimited self-renewal and pluripotency to differentiate into various cells. Since then, Healios has provided UDCs to research institutes and companies around the world as a promising raw material for cellular medicines and verified their potential in relation to a wide range of diseases. Among other cell types, Healios has confirmed the induction of differentiation, hypo-immune character, etc. for [otic neural progenitor cells](#) and [pancreatic  \$\beta\$ -cells](#), and has published certain results of this research, which has been highly evaluated by its partner institutions around the world.

Leveraging this award by CIRM, Healios NA expects to further expand the potential of UDC derived therapies in the United States, where progressive biotech research and development is underway. Please refer to the [“CIRM invests more than \\$42 million in translational-stage research”](#) in the CIRM website for more information on this matter.

Richard Kincaid, President of Healios NA, made the following comment: “We are grateful to CIRM and their team of independent reviewers for recognizing the high potential of our hypo-immune iPSC technology and awarding us with this important grant. We are excited to partner with CIRM to advance innovative regenerative medicine technology for the benefit of patients with unmet medical needs.”

Commenting on the award, Tadahisa Kagimoto, MD, Chairman and CEO of Healios, said: “We are pleased to announce that Healios NA has been awarded this grant by CIRM, the largest non-profit organization promoting regenerative medicine in the United States, in support of our UDC platform technology. CIRM has funded 68 clinical trials and more than 30 research projects. We are building our UDC platform to become a de facto standard technology made available for use in collaborative research and licensing to greatly advance the world of

regenerative medicine.”

These grants are awarded for each milestone reached with CIRM. We will promptly announce any matters that should be disclosed in the future.

**About CIRM:**

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission. To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today’s most promising stem cell technologies. With \$5.5 billion in funding and more than 161 active stem cell programs in our portfolio, CIRM is the world’s largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

<https://www.cirm.ca.gov>

**About Healios:**

Healios is Japan’s leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan, where it has established a proprietary, gene-edited “universal donor” induced pluripotent stem cell (iPSC) line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need. Healios’ lead iPSC-derived cell therapy candidate, HLCN061, is a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene editing. Its near-term pipeline includes the somatic stem cell product HLCM051, which has been evaluated in Japan in Phase 2/3 and Phase 2 trials in ischemic stroke and acute respiratory distress syndrome (ARDS), respectively, and is currently being advanced globally by Healios in ARDS. Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593).

<https://www.healios.co.jp/en>