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Company Name: HEALIOS K.K.  
Representative: Hardy TS Kagimoto,  
Chairman & CEO  
(TSE Mothers Code: 4593)

## **Establishment of a new Healios research facility at the BMA To accelerate and strengthen iPS cell pipeline development**

HEALIOS K.K. ('Healios') has established a new research facility inside the Business Support Center for Biomedical Research Activities (the "BMA"), which is a central facility of the Kobe Biomedical Innovation Cluster, to accelerate and strengthen its iPS cell regenerative medicine focused research and development projects.

At the newly established research facility at the BMA, P2 level recombinant DNA experiments\*<sup>1</sup> and BSL2 level cultivations\*<sup>2</sup> are possible.

Healios is developing regenerative medicine products in-house using iPS cells, including proprietary Universal Donor Cells (UDCs), which are next generation iPS cells created with gene-editing technology to engineer a low risk of immune rejection\*<sup>3</sup> regardless of HLA type\*<sup>4</sup>. Among Healios' programs an allogeneic UDC-derived gene-edited natural killer (NK) cell therapy (development code: HLCN061) is developed to treat solid tumors. Due to the scope of its activities, Healios has needed to expand the space available to conduct evaluation experiments using cell cultures and laboratory animals. Currently Healios' Kobe laboratories are in the Translational Research Center for Medical Innovation and in the KIMEC Center Building, both of which are in Kobe's Port Island. In addition to these existing facilities, the establishment of a new research facility inside the BMA expands our capacity to perform experiments and thereby promotes the acceleration of this important program and its pipeline more generally.

<Overview of the new research facility >

- (1) Address: 4F Research Building,  
Business Support Center for Biomedical  
Research Activities (BMA)  
1-5-5 Minatojima Minamimachi,  
Chuo-ku, Kobe City
- (2) Area: 150m<sup>2</sup>
- (3) Research activities: Cell culture, recombinant DNA,  
animal experiments, other
- (4) Start of operation: From June 2020



\*1: P2 level recombinant DNA experiments. There are guidelines (Guidelines for Research Involving Recombinant DNA Molecules) set by the country to ensure the safety of recombinant DNA research. The guidelines require the physical sealing-in of recombinant bodies so that they do not leak outside experiment areas. Research facilities generally conduct P1 and P2 level experiments. For P2, doors and windows must be closed to prevent dispersion, and installments of safety cabinets and high-pressure steam sterilizers are also necessary.

\*2: BSL2 level cultivations. For human-derived cells, there are risks of contamination by unknown viruses, so generally, BSL2 level handling based on WHO's "Laboratory Biosafety Manual" is recommended. BSL2 level facilities/equipment are required to deal with many microorganisms safely by excluding bacteria and viruses that can cause serious diseases if they infect humans. BSL2 level handling involves the posting of biohazard warnings, the installation of high-pressure steam sterilizers, and only allows for entry of authorized personnel.

\*3: Immune rejection

This is a response involving the immune cells during the transplantation of cells or an organ derived from a different individual which results in the transplanted cells or organ (implant) being recognized as a foreign entity and attacked/rejected by the immune cells.

\*4: HLA Type

HLA (Human Leukocyte Antigen) is an important molecule expressed in all human cells that is involved in how our immune system functions. Any substance in an individual's body with HLA type that differs from the individual's own is recognized as a foreign substance, which triggers an immune response that rejects and attacks that substance. Therefore, ensuring a match of HLA types is extremely important in organ transplantation.

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