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Outline of the Current Status of the Company, Short-term and Long-term Strategy

HEALIOS K.K. ("Healios") announced on June 13, 2019 certain changes to the joint development framework with Sumitomo Dainippon Pharma Co., Ltd. in relation to iPSC regenerative medicine field product HLCR011 that were made to enable to the company to focus near-term on its two ongoing clinical trials in the field of somatic regenerative medicine. On the same day it announced the consideration of establishing a venture capital fund.

As per the following, we outline the current status of the company and its vision for the future – covering both short-term and long-term goals.

[Short-term Goals]
In accordance with our plans to leverage Japan's conditional and time-limited authorization system, and to streamline our capabilities as a pharmaceutical company by introducing and commercializing products which are ready to enter clinical trials as quickly as possible, Healios entered into an alliance with Athersys, Inc. ("Athersys") and started a clinical trial for ischemic stroke in Japan. Subsequently, we commenced a clinical trial for acute respiratory distress syndrome (ARDS). These two trials demonstrate our progress in relation to our short-term goals.

However, running two clinical trials simultaneously requires significant effort and resources. Consequently, instead of running a third trial solely by ourselves, we determined that it was appropriate to work toward the practical application of HLCR011 with the support of our joint development partner, by transitioning to a framework in which they would lead the clinical trial.

Here we summarize the progress of the two ongoing clinical trials.

<Phase 2/3 clinical trial for ischemic stroke in Japan>
August 2016: Submitted a clinical trial notification
November 2017: Enrolment of first patient
May 2019: Completed setup of investigational product (IP) at all clinical trial sites (more than 40 sites)

While we initially envisioned expanding the number of clinical trial sites at an earlier stage, due to previously disclosed issues involving the production and supply of investigational product by our partner, more time than expected was required. In addition, due to the acute stage nature of the indication, enrolling patients at the clinical trial sites has proven to be more challenging than expected because of the burden it places on the people involved at the sites. Given this combination of

circumstances, there is an increased possibility that the enrollment of trial subjects may take approximately half a year longer than initially projected. However, as a lengthy clinical trial period would also increase the load on the stakeholders, we plan to consult and pursue new measures to complete the clinical trial as soon as possible.

<Phase 2 clinical trial for ARDS in Japan>
October 2018: Submitted a clinical trial notification
April 2019: Enrolment of first patient

As these two trials use the same product, we are leveraging our experience in ischemic stroke and currently working to efficiently expand the clinical trial sites for ARDS. Since there are approximately 10,000 cases of onset annually and roughly one-third of these patients are pneumonia-induced ARDS patients who are projected to be suitable for the trial, we are considering to conduct the trial at more than 25 sites for the enrollment of 30 subjects, with the aim of completing the enrollment of the trial subjects as quickly as possible.

[Mid to Long-term Goals]
In the mid to long-term, Healios aims to use the earnings and its business position as a pharmaceutical company gained through achieving our short-term goals to establish the following stem cell platforms and deliver innovative treatments to patients. Regarding the development of new product lines, we will consider a flexible development framework with partners in addition to in-house development.

a) iPS cells with gene editing technology, and new transplant techniques
We aim to avoid immune rejection by using gene editing technology to create iPS cells which are not recognized by the patient's immune cells and make this the focus of our next-generation technology platform. Furthermore, we will develop safer and more effective regenerative medicine products by combining these next-generation iPS cells with new transplant techniques, for example in organ bud technology applications, and aim to develop treatments for diseases which currently have no effective treatments.

b) Immuno-oncology with gene editing technology
We aim to genetically modify iPS cells to create more effective immune cells and utilize them for cancer immunotherapy. We are conducting in-house R&D for next generation immuno-oncology based on the view that the use of iPS cells is likely to enable the reliable mass production of immune cells with greatly increased lethality in comparison with regular immune cells.

c) Development of efficient manufacturing methods
To enable the practical application of treatments using new cell technologies like the above, improvements in manufacturing methods, such as automated culturing equipment, 3D culturing technology, and low-cost production of culture medium will also be necessary. While we expect success in this area in the future, it will require time and money to develop transplant and manufacturing methods, and we aim to build a flexible and effective framework rather than insisting on in-house development.

d) Expected effects of establishing a venture capital fund
In addition to the potential financial return from investments made by the venture capital fund, we anticipate our fund activities may provide various benefits supportive of the achievement of our company's long-term goals, including the acquisition of high quality information; the potential for

opportunities to build relationships with promising ventures, possibly leading to licensing or other synergistic opportunities; and potential funding for in-house technologies that we decide to carve out. A fund dedicated team will spearhead fund efforts, allowing the company to focus on the execution of its goals while simultaneously and efficiently continuing to build its engagement with important emerging technologies and companies.

Although outlined here again, the general strategic framework remains consistent with the announcement we made in March 2018 when we expanded the collaboration with Athersys. Within this larger strategy, we will make decisions as the circumstances evolve, and work toward achieving our mission, “To foster a ‘Life Explosion’ that enriches the lives of people around the world”