LSI Medience Corporation

THE KAITEKI COMPANY
Mitsubishi Chemical Holdings Group

For Immediate Release

In Response to A Worldwide Paradigm Shift in Anti-Cancer Drug Development: Initiation of a Japanese Cancer Patient-derived Xenograft (J-PDX) Repository Establishment Program

March 26, 2018
LSI Medience Corporation

Tokyo, Japan, March 26th, 2018 -- LSI Medience Corporation (LSIM, President: Akio Ito), a Mitsubishi Chemical Holdings Group company, the National Cancer Center of Japan (NCC, Board Chairman: Hitoshi Nakagama), and the National Institute of Biomedical Innovation, Health and Nutrition (NIBIOHN, Board Chairman: Yoshihiro Yoneda), are pleased to announce the commencement of the J-PDX Program supported by the Japan Agency for Medical Research and Development (AMED) on March 7, 2018.

The objective of this program is to create an international-level research repository of Japanese Patient-Derived Xenografts (J-PDX) for use in the pharmaceutical industry in addition to nurturing expert personnel to promote academia-industry collaboration in their relevant fields. Three parties collaborate on this project: 1) LSI Medience Corporation (LSIM), which has GLP facilities accredited by the Minister of Health, Labor and Welfare and serves as the sole Japanese CRO with the PDX expertise, 2) the National Institute of Biomedical Innovation, Health and Nutrition (NIBIOHN), which was the first to establish a variety of PDX models in severe-combined immunodeficient mice and possesses an international-level biomedical institute, and 3) the Japanese National Cancer Center (NCC) which has two National Core Clinical Hospitals and Japan's largest oncology research institute.

Cancer is the leading cause of death in Japan, and the number of cases are steadily increasing due to a rapidly aging population. Currently, oncology drug development is extremely difficult; one of the main obstacles is the low clinical predictability of lengthy non-clinical studies, i.e., tumor-derived cell lines and their xenograft mouse models. By contrast, the PDX model is established by transplanting a patient's fresh tumor specimen into mice. The transplanted xenograft retains the characteristics and heterogeneity of

original tumors - histology, somatic mutations, gene expression, drug resistance etc., allowing excellent predictability of clinical outcome. In the United States and Europe, the use of PDX models by the pharmaceutical industry is sky-rocketing, resulting in the rapid replacement of the existing models in oncology drug screening.

In accordance with the requests of the Pharmaceuticals and Medical Devices Agency (PMDA), we are planning to: 1) refine bio-ethical rules for the industrial use of J-PDXs, 2) establish a world-class J-PDX repository that includes Japan's top 5 cancers (lung, colon, breast, stomach, uterus) in addition to prostate, pancreatic and rare cancers, along with the associated donors' clinical information, 3) set criteria for the establishment and use of the J-PDX repository, 4) create standard operating procedures for the storage and use of J-PDXs in GLP-compliant, non-clinical studies, and 5) establish a research platform for basic and applied PDX science.

Along with this project, the NCC is planning to collaborate with pharmaceutical companies to conduct 'co-clinical studies', in which the clinical outcome of a patient can be compared with the matched PDX model outcome to increase R&D success rate, and the NIBIOHN will assist pharmaceutical companies in identifying new drug targets and leading candidates by employing their state-of-the-art drug discovery technologies.

< Contact Information for Press-related Inquiries>

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An inquiry period: From April 16, 2018 to May 31, 2018