Hitachi and ThinkCyte announce collaboration to develop an AI-driven cell analysis and sorting system

Tokyo July 1, 2020. Hitachi, Ltd (TSE: 6501, "Hitachi") and ThinkCyte, Inc. ("ThinkCyte") today announced that they have entered into a collaboration focused on developing an artificial intelligence (AI)-driven cell analysis and sorting system. Hitachi provides a broad range of solutions such as automated cell culture technologies to pharmaceutical companies in the value chain[1] of the regenerative medicine and cell therapy industry. Through the addition of this cell analysis and sorting system to the value chain, Hitachi continues contributing to cost reductions in the manufacturing of regenerative medicine and cell therapy products. Further, Hitachi and ThinkCyte are promoting collaboration with pharmaceutical companies and research institutes working in the field of regenerative medicine and cell therapy to expedite the development of the system toward commercialization.

The practical applications of regenerative medicine and cell therapy using cells for treatment have been expanding rapidly with the first regulatory approval of CAR-T[2] therapy for leukemia in 2017 in the United States and 2019 in Japan. The global market for regenerative medicine and cell therapy is expected to grow from US$ 5.9 billion (JPY 630 billion) in 2020 to US$ 35.4 billion (JPY 3.8 trillion) in 2025[3]. In order to scale up treatment using regenerative medicine and cell therapy products, it is critical to ensure consistent selection and stable supply of high quality cells in large quantities and at a low costs.

Hitachi has been providing large-scale automated induced pluripotent stem (iPS) cell culture equipment, cell processing facilities (CPFs), manufacturing execution systems(MES), and biosafety cabinets among other products to pharmaceutical companies and research institutes, and has developed a value chain to meet a variety of customer needs in the regenerative medicine and cell therapy industry. Hitachi has also been carrying out collaborative research projects with universities, research institutes, and other companies to develop core technologies for pharmaceutical manufacturing instruments and *in vitro* diagnostic medical devices, prototyping for mass production, and working on manufacturing cost reduction and the development of stable and reliable instruments.

ThinkCyte has been performing research and development focused on high-throughput single cell analysis and sorting technology to precisely analyze and isolate target cells. While such single cell analysis and sorting technologies are vital to life science and medical research, it has been thought impossible to achieve high-throughput cell sorting based on high-content image information of every single cell. ThinkCyte has developed the world's first Ghost Cytometry™ technology to achieve high-throughput and high-content single cell sorting[*4] and has been conducting collaborative research projects with multiple pharmaceutical companies and research institutes to utilize this technology in life science and medical fields.

Hitachi and ThinkCyte have initiated a joint development of the AI-driven cell analysis and sorting system based on their respective technologies, expertise, and know-how. By combining ThinkCyte's high-throughput and high-content label-free single cell sorting technology and Hitachi's know-how and capability to producing stably operative instruments on a large scale, the two companies will together develop a novel reliable system to enable high-speed label-free cell isolation with high accuracy, which has been difficult to achieve with the existing cell sorting techniques, and to realize stable, low-cost and large-scale production of cells for regenerative medicine and cell therapy.

Hitachi and ThinkCyte will further advance partnerships with pharmaceutical companies and research institutes that have been developing and manufacturing regenerative medicines and cell therapy products in Japan and other countries where demand is expected to be significant, such as North America, in order to make this technology a platform for the production of regenerative medicines and cell therapy products. At the same time, taking advantage of the high-speed digital processing technologies cultivated through the development of information and communication technology by the Hitachi group, Hitachi will integrate this safe and highly reliable instrument in its value chain for regenerative medicine and contribute to the growth of the regenerative medicine and cell therapy industry.

Note:

*1. Cell manufacturing processes, including cultivation, selection, modification, preservation, product quality control, etc.

*2. Chimeric Antigen Receptor T cells that have been genetically engineered to produce an artificial T-cell receptor for use in immunotherapy.

*3. Division of Regenerative Medicine, Japan Agency for Medical Research and Development, The final report for market research on regenerative medicine and gene therapy (2020).

*4. S, Ota et al., Ghost Cytometry, Science, 360, 1246-1251 (2018).

About the AI-driven cell analysis and cell sorting technology

ThinkCyte has developed high-throughput image-based cell sorting technology based on the Ghost Cytometry technology by integrating the principles of advanced imaging technology, machine learning, and microfluidics. By applying structured illumination to cell imaging, structural information of a single cell can be converted to one-dimensional waveforms for high-throughput data analysis. Based on the judgment of a machine-learning (AI) model developed using the waveform data, target cells are isolated in a microfluidic device with high throughput and with minimal damage to the cells.

This data analysis approach eliminates time-consuming image reconstruction processes and allows high-throughput image-based single cell sorting, enabling the discrimination of cells that were previously considered difficult to distinguish by the human eye. Conventional cell sorting methods rely on the use of labels such as cell surface markers for cell sorting; in contrast, ThinkCyte's technology can sort cells without such labels by employing this unique approach. In addition to the field of regenerative medicine and cell therapy, this technology can also revolutionize drug discovery and *in vitro* diagnostics fields.

About Hitachi, Ltd.

Hitachi, Ltd. (TSE: 6501), headquartered in Tokyo, Japan, is focused on its Social Innovation Business that combines information technology (IT), operational technology (OT) and products. The company's consolidated revenues for fiscal year 2019 (ended March 31, 2020) totaled 8,767.2 billion yen ($80.4 billion), and it employed approximately 301,000 people worldwide. Hitachi drives digital innovation across five sectors - Mobility, Smart Life, Industry, Energy and IT - through Lumada, Hitachi's advanced digital solutions, services, and technologies for turning data into insights to drive digital innovation. Its purpose is to deliver solutions that increase

social, environmental and economic value for its customers. For more information on Hitachi, please visit the company's website at https://www.hitachi.com.

About ThinkCyte, Inc.

ThinkCyte, headquartered in Tokyo, Japan, is a biotechnology company, which develops innovative life science research, diagnostics, and treatments using integrated multidisciplinary technologies, founded in 2016. The company focuses on the research and development of drug discovery, cell therapy, and diagnostic platforms using its proprietary image-based high-throughput cell sorting technology In June 2019, the company was selected for J-Startup by the Ministry of Economy, Trade and Industry of Japan. For more information on ThinkCyte, please visit the company's website at https://thinkcyte.com.

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