News Release
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Hitachi's new cell design platform, which integrates digital and biotechnology, will streamline drug discovery for cell and gene therapy

Generating value through the technology evaluation and co-creation with pharmaceutical companies, biotech startups and academia for overcoming cancer and intractable diseases

Tokyo, May 13, 2025 Hitachi, Ltd. (TSE:6501, "Hitachi") has newly developed "DesignCell® development platform" technology combining digital and biotechnology, in support of pharmaceutical companies and biotech startups engaged in the generation of cell and gene therapy medications.*1 The platform uses generative AI to design gene sequences, and links to high-throughput cell screening, raising the number of cells that can be designed and evaluated from a few tens of cells per year currently to 100,000 cells per year with this system. It is expected to shorten the time needed for exploratory research in development of cell therapy products, especially support efficient development of CAR-T cells*2 for safe and highly effective cancer treatment.

Working with pharmaceutical companies and academia, Hitachi will seek to evaluate the effectiveness of the technology and contribute to overcoming cancer and other intractable diseases.

The results of this development project are to be presented in part at the Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) being held in New Orleans (Louisiana, USA) from May 13 to 17, 2025.

*1 Various pharmaceutical products that use cells and genes to treat diseases.
*2 Chimeric antigen receptor (CAR) T cells: T cells that have been genetically modified to attack cancer cells. T cells play a key role in the immune system, fighting viruses and cancer cells to protect the body.

Background and issues

Regenerative medicine and cell/gene therapy markets have grown rapidly in recent years, and are expected to reach a scale of around 7.4 trillion yen by 2030.*3 The spread of these modalities, however, has been hampered by their high cost and the limited number of diseases to which they are applicable. Enhancing the efficiency of developing cell therapy products is particularly crucial for tackling lacking effective treatments, such as advanced cancer, solid carcinomas, and rare diseases of the nervous system. With existing research approaches, however, comprehensive cell design and evaluation take a long time; moreover, only modifications in a very limited region of a targeted gene where a maximization of the efficacy is expected can be attempted at one time. For such reasons, time required for development is a major issue to be overcome.

*3 Source: Japan Agency for Medical Research and Development (AMED) 2019 fiscal year market survey of regenerative medicine and gene therapy (Arthur D. Little Japan, 2020; in Japanese)

Features of the developed technology

To address this challenge, Hitachi has developed an innovative “DesignCell® development platform” that integrates digital technology with biotechnology. This method supports pharmaceutical companies and biotech startups in creating cell therapy products more efficiently. The main features of the newly developed technology are as follows.

1. Efficient design and development of therapeutic drugs making use of gene sequence generative AI

Hitachi’s original gene sequence generative AI, applying natural language processing technology, efficiently extracts statistical patterns from vast amounts of gene sequence data based on evolutionary conservation[*4] and generates a new CAR gene sequence database. Moreover, by learning from experimental data linking gene sequences and cellular functions, Hitachi's platform can search for CAR gene sequences with maximized activity in fighting cancer cells from 100 million possible combinations.

2. High-throughput cell evaluation system enabling large-volume data acquisition

Hitachi's high-throughput cell evaluation system is combined with pool screening technology[*5] that able to evaluate CAR-T cells at the single-cell level, and array screening technology[*6] that employs robotics for automating all the processes from gene introduction in a cell to analysis of the cell function. The system is therefore capable of evaluating cells by various indicators at a rate of 100,000 types/year, the largest scale in the industry.[*7] Able to evaluate the cytotoxic activity[*8] of 14,000 kinds of CAR-T cells at once, the system has achieved large-scale acquisition of activity data associated with CAR gene sequences. By thus enabling the evaluation of modifications to all areas of CAR gene sequences and large numbers of modification combinations, it will accelerate the design and development of highly effective transgenic cells.

3. An original DBTL cycle using gene sequence generative AI and cell evaluation data

The above technologies have realized a Hitachi-original DBTL cycle, consisting of gene design using gene sequence generative AI (**D**esign), high-throughput introduction of genes in cells, automated by robotics (**B**uild), large-scale and precise analysis of cell functions, combining pool screening and array screening (**T**est), and analysis of the correlations between gene sequences and cell functions (**L**earn). By running this cycle multiple times, highly active CAR-T cells against cancer cells can be designed efficiently. Consequently, such cells showed also in animal testing to have higher tumor shrinking effectiveness than conventionally designed cells.

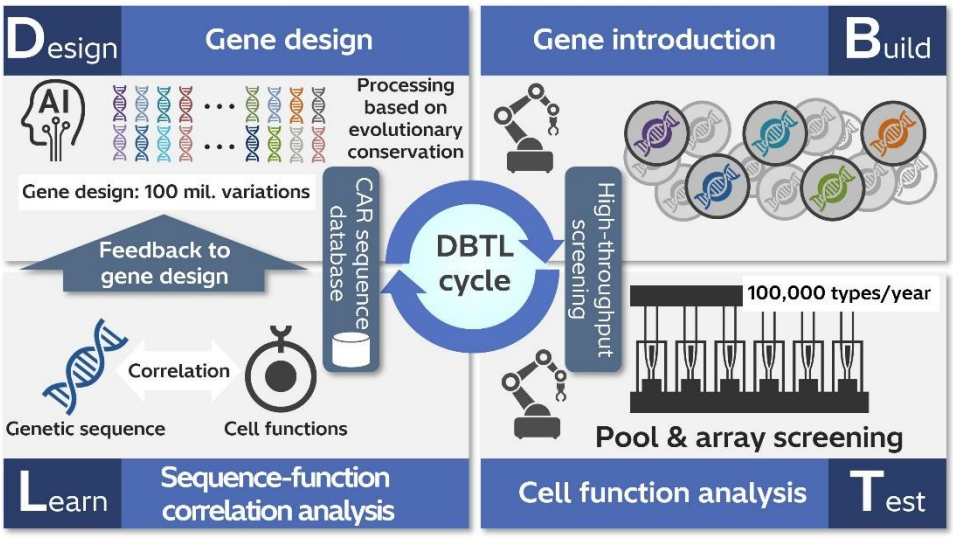

Figure 1. Hitachi's original DBTL cycle by means of gene sequence generative AI and high-throughput screening technology

*4 The thinking that since the gene sequence of a given molecule (in this case, CAR) is shared among living creatures, that sequence must be important to other living creatures for maintaining the molecular functions.
*5 A method of analyzing a large number of genetically modified cells at once, by combining phenotypic analysis and genetic analysis to obtain data associating phenotypes with modified gene sequences. Using an optofluidic system, Hitachi verifies the activity of CAR-T cells on cancer cells at the single-cell level.
*6 A high-reproducibility method for verifying the effectiveness of CAR-T cells on cancer cells under multiple different conditions. The processes from CAR-T cell production to evaluation are automated by robotics.
*7 As of April 30, 2025, according to Hitachi surveys.
*8 The activity of immune cells in directly attacking and killing abnormal cells such as cancer cells or those infected with a virus.

Comment by Koji Tamada, professor in the Graduate school of medicine, Yamaguchi University, and director of the Yamaguchi University Research Institute for cell design medical science

CAR-T cell therapy, which shows high efficacy for treating hematological cancer, has already been approved as a gene & cell therapy drug and is undergoing many clinical trials aimed at expanding its application to autoimmune diseases. As for solid carcinomas, which make up a large portion of cancers, while substantial progress is being seen thanks to active research and development, further technology development is needed for the sake of outstanding efficacy and safety. To design optimized CAR-T cells, many different combinations of control factors must be verified. The high-throughput discovery system Hitachi is working on is expected to play an important role in this regard.

Looking ahead

In collaboration with pharmaceutical companies, biotech startups and academia, Hitachi will seek to verify the effectiveness of the technology, toward more efficient generation of cell and gene therapy medications, for contributing to the successful treatment of cancer and intractable diseases. Details about our platform and experimental results are to be presented in part at the Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) being held in New Orleans (Louisiana, USA) from May 13 to 17.

About Hitachi, Ltd.
Through its Social Innovation Business (SIB) that brings together IT, OT(Operational Technology) and products, Hitachi contributes to a harmonized society where the environment, wellbeing, and economic growth are in balance.

Hitachi operates globally in four sectors – Digital Systems & Services, Energy, Mobility, and Connective Industries – and the Strategic SIB Business Unit for new growth businesses. With Lumada at its core, Hitachi generates value from integrating data, technology and domain knowledge to solve customer and social challenges. Revenues for FY2024 (ended March 31, 2025) totaled 9,783.3 billion yen, with 618 consolidated subsidiaries and approximately 280,000 employees worldwide. Visit us at www.hitachi.com.

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