

December 5, 2024
Japan Tissue Engineering Co., Ltd.
Sysmex Corporation

Sysmex and J-TEC Sign a Basic Agreement to Advance Manufacturing Capabilities for Regenerative Medicine and Cell Therapy

Japan Tissue Engineering Co., Ltd. (HQ: Gamagori, Aichi Prefecture; President & CEO: Ken-ichiro Hata; hereinafter “J-TEC”) and Sysmex Corporation (HQ: Kobe, Japan; President: Kaoru Asano) announced that they signed a basic agreement (“the Agreement”) on December 3, 2024, with the aim of advancing (i.e., mechanizing and automating) manufacturing capabilities for regenerative medical products by utilizing innovative technologies, in order to accelerate the industrialization of regenerative medicine and cell therapy and to enhance sustainability. Going forward, both companies will start concrete strategic collaboration based on this Agreement.

One of the major challenges in the industrialization of regenerative medicine and cell therapy is the difficulty of manufacturing products from living cells. In particular, autologous cell products¹ derived from patients’ own cells need to be manufactured to accommodate the non-uniform character of the cells from each patient. As a result, it is extremely challenging to mechanize and automate the manufacturing processes in a standardized manner. This creates a bottleneck in expanding the scale of production and enhancing efficiency in the regenerative medicine and cell therapy industry, and the transfer of manual manufacturing techniques therefore becomes an issue that directly affects the sustainability of the business.

J-TEC was the first company in Japan to develop and obtain approval of regenerative medical products, making it a pioneer in regenerative medicine. In particular, it has been working to commercialize and utilize autologous cell products in society. Based on the experience and knowledge gained in this process, the company has established a platform to stably supply products while maintaining high quality.

Sysmex has contributed to the evaluation of cell functions by providing quality control testing² capable of non-destructively analyzing cell characteristics, as well as Internet of Things (IoT) and other robotic technologies, to academic institutions and pharmaceutical companies that develop regenerative medical products. The company has also been working on automating manufacturing processes for the pipeline of our group companies and strategic partners.

Both companies have been discussing ways to leverage their individual strengths to solve issues in the regenerative medicine and cell therapy industry, based on the technology and know-how they have developed through their respective business activities. As part of this, a basic agreement was signed on December 3, 2024, with the aim of enhancing manufacturing capabilities for regenerative medicine and cell therapy through innovative technologies.

Through open innovation based on the strengths of both companies, they will contribute to the sustainable development of Japan's regenerative medicine and cell therapy industry by realizing the mechanization and automation of manufacturing processes for regenerative medical products, which is a key issue in the regenerative medicine and cell therapy industry.

We anticipate that the impact of this initiative on our financial performance for the fiscal year ending March 2025 will be minimal. However, we believe it will contribute to enhancing our corporate value in the medium to long term.

Terminology

- 1 Autologous cell products:
Regenerative medical products manufactured from patients' own living cells.

- 2 Quality testing that allows non-destructive cell analysis:
Testing that enables the analysis of cell quality without destroying the cells themselves.
Since the cells do not need to be destroyed, it allows for the efficient and accurate testing of cell products in a short period of time.

About Japan Tissue Engineering Co., Ltd.

J-TEC is a maker of regenerative medical products. Our vision is "Creating a Future for Regenerative Medicine", and we have been a member of the Teijin Group since March 2021. As the top runner in Japan's regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ✓ Approved Oct. 2007: Autologous Cultured Epidermis JACE® – Japan's first regenerative medical product
- ✓ Approved July 2012: Autologous Cultured Cartilage JACC® – Japan's first regenerative medical product in the plastic surgery field
- ✓ Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC® – Japan's first regenerative medical product in the ophthalmology field
- ✓ Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
- ✓ Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN

About Sysmex Corporation

Sysmex Corporation, headquartered in Kobe, Japan, is a global leader in *in vitro* diagnostics. Since its foundation in 1968, Sysmex has focused on diagnostics as the core of its business, and today, it supports the health of people in over 190 countries and regions worldwide. Sysmex continues to innovate in diagnostics, and to collaboratively create unique values in the areas of personalized medicine and novel treatments, under its long-term vision of "Together for a better healthcare journey." Through its unique technology, solutions, and co-creation with various partners, Sysmex delivers new value and addresses the universal desire of people to live longer and healthier lives. For more information about Sysmex, please visit www.sysmex.co.jp/en/.

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