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PRESS RELEASE

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Ajinomoto Co.'s iPSC Culture Medium Technology Contributes to the Practical Application of Cuorips Inc.'s iPSC-Derived Cardiomyocyte Sheets

World's First Treatment Using an iPSC-Derived Regenerative Medical Product Begins

TOKYO, October 16, 2026 – Ajinomoto Co., Inc. ("Ajinomoto Co.") has supported the research and practical application of regenerative medicine and cell therapy using induced pluripotent stem cells (iPSCs) since 2015 through the supply of StemFit™, a culture medium for regenerative medicine. Recently, iPSC-derived cardiomyocyte sheets RiHEART® developed by Cuorips Inc.("Cuorips") have received conditional and time-limited approval as an iPSC-derived regenerative medical product from Japan's Ministry of Health, Labour and Welfare. Subsequently, in September 2026, for the first time ever, a patient was treated with RiHEART®. In the development and manufacture of RiHEART®, Ajinomoto Co.'s StemFit™ (StemFit™ AK03N) is used as a culture medium for iPSCs. Through the provision of StemFit™, Ajinomoto Co. contributes to advances in regenerative medicine, as exemplified by the world's first practical application of an iPSC-derived regenerative medical product.

StemFit™ AK03N

The newly approved iPSC-derived cardiomyocyte sheets RiHEART®[1] is intended for patients with severe heart failure, a particularly serious condition with limited treatment options among the approximately 720,000 heart failure patients in Japan.[2] Until now, definitive treatment has been considered difficult except through heart transplantation, and a different approach has therefore been needed. This new iPSC-based treatment is an innovative approach that could significantly change the current treatment paradigms by improving cardiac function through substances secreted by cell sheets. In the clinical trial, improvements in symptoms were observed following transplantation of the cardiomyocyte sheets produced from iPSCs into patients with severe heart failure.[3] This marks a historic step in the advancement of iPSC technology from the research stage to practical application, made possible by Cuorips's iPSC-derived cardiomyocyte cell sheets transplantation technology.

1) iPSC-Derived Cardiomyocyte Patches| Cuorips Inc.
2) Ministry of Health, Labour and Welfare, *Patient Survey 2023: Classification of Diseases* (in Japanese).
3) Osaka University's report on transplantations conducted in the latter half of the investigator-initiated clinical trial of cardiomyocyte cell sheets derived from iPSCs (in Japanese).

Ajinomoto Co.'s StemFit™, which supports such iPSC technologies, is a culture medium containing factors essential for iPSC culture in optimal proportions. Leveraging its expertise in "AminoScience" cultivated over many years of research and development in food- and pharmaceutical-grade amino acids, Ajinomoto Co. has supported research and development in regenerative medicine by establishing component design and quality control technologies suitable for iPSC culture. StemFit™, contains no human- or animal-derived raw materials, and all of its components and their concentrations are clearly defined, thereby providing the high level of safety and excellent raw material traceability required for the practical application of regenerative medicine. In addition to ensuring a stable supply of culture medium, Ajinomoto Co. also addresses needs associated with commercialization and large-scale manufacturing through registration with the Pharmaceuticals and Medical Devices Agency (PMDA)'s Drug Master File System[4] and providing regulatory support.[5]

4) A system for the prior registration with the PMDA of information regarding the quality and manufacturing methods of raw materials used in the production of pharmaceuticals.

5) Provision of information required for regulatory submissions and assistance in responding to inquiries from regulatory authorities.

In the healthcare area, one of the four focused growth areas set forth to achieve its Medium-Term ASV Initiatives 2030 Roadmap, the Ajinomoto Group is supporting the advancement of cutting-edge fields through a broad range of businesses, including the provision of culture media for regenerative medicine, the manufacture of pharmaceutical-grade amino acids, and contract development and manufacturing organization (CDMO) services comprising contract development and manufacturing of pharmaceuticals. The contribution of StemFit™ to regenerative medicine described above is one example of these initiatives. Going forward, with a view to further practical application and commercialization in the field of regenerative medicine, the Ajinomoto Group will continue to develop new products designed for large-scale cell culture and pursue other initiatives based on "AminoScience" with the aim of improving the quality of life of patients and their families, while contributing to the well-being of all human beings, our society and our planet through business growth in the healthcare area.

Reference

■ Overview of Cuorips Inc.

(1) Company Name: Cuorips Inc.
(2) Location: O-Nexus, Nakanoshima Qross 8F, 4-3-51 Nakanoshima, Kita-ku, Osaka-shi, Osaka
(3) Established: March 21, 2017
(4) Representative: Takayuki Kusanagi, President and CEO
(5) Number of Employees: 51 (as of March 31, 2026)
(6) Business Description: Development and commercialization of human iPSC–derived cardiomyocyte cell sheets
(7) Press Release: https://www.cuorips.co.jp/news-en/200261001

■ Ajinomoto Co.'s Regenerative Medicine Business

Press release dated June 9, 2017
Ajinomoto Co. Confirms Strong iPSC Growth Performance of StemFit™ AK03N, a Culture Medium for Clinical Research
https://www.ajinomoto.co.jp/company/jp/presscenter/press/detail/2017_06_09.html (in Japanese)

Advancing regenerative medicine: StemFit™ helps advance research into safe and reliable therapies
https://www.ajinomoto.com/stories/advancing-regenerative-medicine-stemfit-helps-advance-research-into-safe-and-reliable-therapies

For details on Ajinomoto Co. and the Ajinomoto Group, visit https://www.ajinomoto.com/
For further information, please contact: HERE