

News Release

July 17th, 2025

Human Life CORD Japan Inc.

Phase II Clinical Trial Results for HLC-001 for Non-Infectious Pulmonary Complications after Hematopoietic Stem Cell Transplantation Published in International Journal

– World’s first study using umbilical cord-derived cells –

Human Life CORD Japan Inc. (President and CEO: Masamitsu Harata, Headquarters: Chuo-ku, Tokyo, Japan, hereinafter referred to as “Human Life CORD”), a pioneer in the development of regenerative cell therapies using umbilical cord-derived mesenchymal stromal cells, is pleased to announce that the results of its Phase II clinical trial of HLC-001 for non-infectious pulmonary complications (NIPCs) following hematopoietic stem cell transplantation have been published online in the International Journal of Hematology on July 16, 2025.

This trial had previously achieved its primary endpoint, as announced in the press release dated November 2, 2023. The new publication highlights the clinical significance of the results and their recognition in the international academic community.

The trial was conducted at multiple sites in Japan, targeting patients with idiopathic pneumonia syndrome (IPS)—a severe, steroid-refractory subset of NIPCs. It aimed to evaluate the exploratory efficacy and safety of HLC-001, an intravenously administered umbilical cord-derived mesenchymal stromal cell product. The study achieved a 56-day survival rate of 71.4% (5 out of 7 patients), significantly higher than the historically reported survival rate of 24.5% for standard therapies. In addition, improvements were observed in several patients, including reduced steroid dosage and decreased need for oxygen therapy, and the 100-day survival rate was also sustained.

No serious adverse events were reported. Adverse events considered related to the treatment were manageable. These findings suggest that HLC-001 may serve as a promising new treatment option for patients with IPS.

IPS is one of the most fatal complications following stem cell transplantation, with no established effective treatment for steroid-refractory cases. The trial results provide academic validation for the therapeutic potential of regenerative medicine in this area and represent a significant step forward in clinical development.

Masamichi Yamada, Executive Officer and Chief Scientific Officer (CSO) of Human Life Cord, commented:

“We extend our sincere gratitude to the patients and their families who participated in the trial, as well as to the medical professionals whose expertise and dedication made this study possible. These results demonstrate the potential of umbilical cord-derived cell therapy to address severe post-transplant complications, and we believe they will form the foundation for further medical progress. We will continue working toward realizing innovative therapies that connect the bonds of life from

birth to future hope.”

Based on these results, Human Life CORD will continue discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) to accelerate the clinical implementation of cell therapies using umbilical cord-derived mesenchymal stromal cells for IPS, while also expanding research and development into other rare and intractable diseases

[Publication Details]

Journal: International Journal of Hematology

Title: Intravenous umbilical cord-derived mesenchymal stromal cell therapy may improve overall survival in Japanese patients with idiopathic pneumonia syndrome after hematopoietic stem cell transplantation: a multicenter, single-arm, phase II trial

Authors: Noriko Doki, Nobuharu Fujii, Shinichi Kako, Emiko Sakaida, Yoshinobu Kanda

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■ About Human Life CORD Japan Inc.

<https://humanlifecord.com/>

Human Life CORD JAPAN Inc. manufactures and develops cell products derived from domestically sourced, storable umbilical cords (“cord”), aiming to connect (“cord”) patients with intractable diseases to hope for life where no established treatments currently exist. Looking ahead, aims to contribute to future medicine that prevents severe disease progression and extends healthy lifespans, creating a society where everyone can enjoy a fulfilling life (“Human Life”).

HLC has received numerous accolades, including:

- First Prize and Governor of Tokyo Award at the 1st Tokyo Venture Business Championship (2019)
- Selection as a target company of the “Deep Ecosystem” operated by the Tokyo Metropolitan Government's Startup Ecosystem Tokyo Consortium
- Minister of Health, Labor, and Welfare Award at the 5th Japan Open Innovation Prize (2023)
- Selection for the “J-Startup” program by Japan’s Ministry of Economy, Trade, and Industry (2023)
- Grand Prize in the Startup Category at the Tokyo Chamber of Commerce and Industry’s “Courageous Management Awards” (2024)

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