



MOCHIDA PHARMACEUTICAL CO., LTD.



February 6, 2026

Mochida Pharmaceutical Co., Ltd.
Human Life CORD Japan Inc.

**Announcement of the Submission of Clinical Trial Notification for Phase III Study
of HLC-001, an Umbilical Cord-Derived Mesenchymal Stromal Cell,
for Non-Infectious Pulmonary Complications After Hematopoietic Stem Cell Transplantation**

This material is an English translation of the press release to be issued on February 6, 2026, in Japanese, and the Japanese release is given priority regarding content and interpretation.

Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; President: Naoyuki Mochida; hereinafter "Mochida") and Human Life CORD Japan Inc. (Head Office: Chuo-ku, Tokyo; President & CEO: Masamitsu Harata; hereinafter "Human Life CORD") announce that Mochida has submitted a clinical trial notification of the initiation of Phase III study (hereinafter "the Study") of HLC-001, an umbilical cord-derived mesenchymal stromal cell (hereinafter "the Product").

The Study is a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparative study designed to evaluate the efficacy and safety of the Product in patients with steroid-refractory idiopathic pneumonia syndrome (IPS) among non-infectious pulmonary complications (NIPCs) after hematopoietic stem cell transplantation.

NIPCs after hematopoietic stem cell transplantation are conditions in which lung injury, such as pneumonia, occurs due to non-infectious causes after transplantation. Major NIPCs include IPS, bronchiolitis obliterans (BO) and cryptogenic organizing pneumonia (COP). Among these, steroid-refractory IPS currently lacks effective therapeutic options and is associated with high mortality, highlighting the need for the development of new treatments.

The Product is a regenerative medicine product that utilizes mesenchymal stromal cells (MSCs) derived from umbilical cord, a tissue connecting the placenta and the fetus. It is expected to suppress inflammation in lung tissue through its anti-inflammatory and immunomodulatory effects and promote repair of lung tissue damaged by severe inflammation. Clinical efficacy of the Product in patients with steroid-refractory IPS was suggested in a Phase II study conducted by Human Life CORD. The Product has been designated as an "orphan regenerative medicine product" with a planned indication for NIPCs after hematopoietic stem cell transplantation, mainly on the basis of the results of this study.

Yoshitaka Hosaka, Ph.D., Executive Managing Officer in charge of Business Promotion at Mochida, stated the following: "The Study represents an important initiative to provide a new treatment option for steroid-refractory NIPCs after hematopoietic stem cell transplantation, using HLC-001. Aiming to contribute to medical and healthcare needs, we will

continue to work together with Human Life CORD to steadily advance the development."

Nobutoshi Matsushita, Board Director and COO at Human Life CORD, stated the following:

"Partnering with Mochida Pharmaceutical, which has abundant development experience in the fields of challenging diseases and rare disorders, will not only maximize the value of HLC-001 but also significantly enhance the corporate value of both companies. As Marketing Authorization Holder for Regenerative Medicine Products, our company will ensure the stable supply and quality of study products, delivering new hope to patients in need of treatment options."

Mochida and Human Life CORD will continue their efforts toward obtaining marketing authorization of the Product, with the goal of developing a new treatment using the Product and delivering effective therapeutic options to patients as soon as possible.

■About Mochida Pharmaceutical Co., Ltd. (<https://www.mochida.co.jp/english/>)

Mochida Pharmaceutical Co., Ltd. has been committed to research and development of innovative pharmaceutical products since its establishment in 1913 thus providing distinctive medicines to the medical community. Currently, the core pharmaceutical business focuses its resources on the targeted areas of cardiovascular medicine, gastroenterology, obstetrics and gynecology, and psychiatry while also providing medicines for intractable diseases and generics including biosimilars, to meet medical needs. Additionally, Mochida aims to incorporate new modalities such as cellular therapy to further contribute to unmet medical needs.

■About Human Life CORD Japan Inc. (<https://humanlifecord.com/en/>)

Human Life CORD Japan Inc. manufactures and develops cellular products from domestic and stockable umbilical cords which are connected to the living desire of patients with rare diseases without any established treatment at present, and then leads to future medical treatment aimed at preventing the serious illness that leads to the extension of their healthy life span. The vision is to create a world where growing older is more enjoyable. In 2019 "First Tokyo Venture Corporate Championship Conference" Best Award & Tokyo Metropolitan Governor's Award. Selected as a supplier of the "Deep Ecosystem" operated by the Tokyo Metropolitan Government "Start-up Ecosystem Tokyo Consortium". In 2023, the Ministry of Health, Labor and Welfare was awarded the 5th Japan Open Innovation Award, sponsored by the Cabinet Office.

Contact:

Mochida Pharmaceutical Co., Ltd.

Public Relations, Corporate Planning Department webmaster@mochida.co.jp

Human Life CORD Japan Inc.

Public Relations info@humanlifecord.com