November 14, 2025

For Immediate Release

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Notice Regarding Consolidated Subsidiary (MEDLEAP PHARMA COMPANY LIMITED) Notice Regarding the Initiation of Phase 2 Clinical Trial in Japan for Ferric Maltol (Development Code: ST10) for Pulmonary Arterial Hypertension (PAH)

VITAL KSK HOLDINGS, INC. (hereinafter "the Company") hereby announces that its consolidated subsidiary, MEDLEAP PHARMA COMPANY LIMITED, has announced today (November 14, 2025), as per the attachment, the "Notice Regarding the Initiation of Phase 2 Clinical Trial in Japan for Ferric Maltol (Development Code: ST10) for Pulmonary Arterial Hypertension (PAH)".

The impact of this matter on the consolidated financial results for the fiscal year ending March 2026 (FY2025) has been incorporated into the "Notice Regarding Revision of Consolidated Financial Forecast for the Fiscal Year 2025" announced today. The Company will promptly announce any matters that require disclosure in the future.

Notice Regarding the Initiation of a Domestic Phase II Clinical Trial of "Ferric Maltol (Development Code: ST10)" for Pulmonary Arterial Hypertension (PAH)

November 14, 2025
MEDLEAP PHARMA COMPANY LIMITED

■ Our New Drug Candidate Advances to Phase II Trial

MEDLEAP PHARMA COMPANY LIMITED (Headquarters: Sendai City, Miyagi Prefecture; President and CEO: Yuichi Kobayashi; hereinafter "the company") announces the initiation of a Phase II clinical trial for Ferric Maltol (Development Code: ST10), a new drug candidate for PAH (Pulmonary Arterial Hypertension) patients, in Japan. This trial will be conducted for the purpose of an exploratory study for a Phase III trial, following confirmation by the PMDA of the development plan for the drug as a PAH treatment in Japan, based on its basic and clinical results overseas. With this advancement, the clinical development program has successfully progressed from the preclinical stage to Phase II trials.

Iron supplementation is strongly recommended for PAH patients with iron deficiency anemia according to both European and Japanese guidance (ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension 2022[1] and Japan Pulmonary Hypertension and Pulmonary Circulation Society Guidance 2024[2]) [Recommendation Class I].

【References】
1) Humbert M, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Respir J. 2023; 61(1):2200879.
2) Japanese Pulmonary Hypertension and Pulmonary Circulation Society. Pulmonary Hypertension Treatment Guidance2024.

■ Comment from Medical Expert - Professor Masaharu Kataoka, Second Department of Internal Medicine, University of Occupational and

Environmental Health, Japan School of Medicine

Iron deficiency anemia is highly prevalent in PAH patients and is associated with various clinical manifestations of PAH, including symptoms, exercise tolerance, right heart function, and hemodynamic parameters. Therefore, efficient iron supplementation is recommended. However, existing treatments face challenges in long-term iron supplementation management due to gastrointestinal side effects and low absorption efficiency, creating a need for new therapeutic options. In this context, we look forward to establishing Japan-originated evidence through clinical trials of Ferric Maltol, a completely new compound that overcomes these challenges and enables long-term administration, in PAH patients.

■ Trial Overview

- **Trial Name**: An Exploratory Phase 2 Study to Evaluate the Efficacy and Safety of Ferric Maltol (ST10) in Patients with Pulmonary Arterial Hypertension (PAH)
- **Target Disease**: Pulmonary Arterial Hypertension
- **Trial Design**: Multi-center, randomized, placebo-controlled, double-blind study
- **Number of Subjects**: Approximately 26 (planned)
- **Primary Endpoint**: 12-week 6-minute walk distance change from baseline
- **Secondary Endpoints**: Cardiac function-related efficacy parameters, safety, tolerability, etc.
- **Trial Location**: Japan

■ About Ferric Maltol(Development Code: ST10)

Ferric Maltol (ST10) has been developed and is already marketed in Europe and the United States as an iron deficiency treatment. As a clearly defined novel covalent complex, Ferric Maltol suppresses free iron generation and reduces gastrointestinal irritation through its binding mechanism. It also improves vascular remodeling and tissue damage. In PAH patients, it is expected to improve pulmonary hemodynamics and prognosis. This novel iron compound achieves efficient and reliable absorption, and the U.S. FDA has recognized it as a New Chemical Entity (NCE). Iron (Fe3+) and maltol

form a chemically stable complex that exists as such in the gastrointestinal lumen. The complex only dissociates into iron and maltol at the intestinal absorption site, thereby reducing direct effects of free iron on the gastrointestinal tract. For these reasons, Ferric Maltol can be administered on an empty stomach. It is designed as a novel oral iron preparation that achieves reduced gastrointestinal side effects, improved absorption efficiency, optimized dosing, and reduced iron-related toxicity through optimal blood concentrations. The Company positions this drug as a core pipeline in the pulmonary arterial hypertension field and is advancing clinical plans with global development in view.

■ Future Development Plans

Based on the results of this trial, the Company plans to conduct Phase III trials (Pivotal Study) and proceed with regulatory submission and launch preparations from 2028 onwards.
Through this drug, the Company aims to strengthen its medium to long-term revenue base and enhance corporate value.

■ About MEDLEAP PHARMA COMPANY LIMITED

MEDLEAP PHARMA COMPANY LIMITED, under its philosophy of "Bringing innovation to Japan's medical future through the creation of original pharmaceuticals," contributes to reducing drug lag in Japan through new drug introduction support business, delivering a healthy future to patients and their families. The Company promotes competitive new drug creation through collaboration with domestic and international research institutions and companies.

- Headquarters: 3-3-1 Yaotome, Izumi-ku, Sendai City, Miyagi Prefecture 981-3112
- Representative: President and CEO Yuichi Kobayashi
- Established: September 2025
- Business Activities: Research, development, manufacturing, and sales of pharmaceuticals

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■ Future Outlook

The forward-looking statements in this release are based on information available at present and assumptions deemed reasonable. Actual results may differ significantly due to future trial results, regulatory environment, competitive conditions, and other factors.

■ Contact Information

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