November 9, 2026

For Immediate Release

Company name:	VITAL KSK HOLDINGS, INC.
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	(Securities Code: 3151, TSE Prime Market)
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Notice Regarding Initiation of Domestic Phase 2 Clinical Trial of "Ferric Maltol (Development Code: ST10)" by Consolidated Subsidiary (MEDLEAP PHARMA COMPANY LIMITED) Aiming for an Additional Indication for Pulmonary Hypertension Associated with Chronic Pulmonary Disease

MEDLEAP PHARMA COMPANY LIMITED, a consolidated subsidiary of VITAL KSK HOLDINGS, INC. (hereinafter "the Company"), announced today (November 9, 2026) the attached "Notice Regarding Initiation of Domestic Phase 2 Clinical Trial of 'Ferric Maltol (Development Code: ST10)' Aiming for an Additional Indication for Pulmonary Hypertension Associated with Chronic Pulmonary Disease."

The impact of this matter on the Company's consolidated financial results for the fiscal year ending March 2027 (fiscal year 2026) is expected to be minor. Should any new matters requiring disclosure arise in the future, the Company will promptly announce them.

Reference:

1. Press Release dated April 22, 2025
   Notice Regarding Conclusion of Exclusive License Agreement for the Development and Sale of ACCRUFeR®, an Iron Deficiency Treatment Created by Shield Therapeutics plc, by Consolidated Subsidiary (VITAL-NET, Inc.)
2. Press Release dated November 14, 2025
   Notice Regarding Initiation of Domestic Phase 2 Clinical Trial of "Ferric Maltol (Development Code: ST10)" for Pulmonary Arterial Hypertension (PAH) by Consolidated Subsidiary (MEDLEAP PHARMA COMPANY LIMITED)

Aiming for an Additional Indication for Pulmonary Hypertension Associated with Chronic Pulmonary Disease
Notice Regarding Initiation of Domestic Phase 2 Clinical Trial of "Ferric Maltol (Development Code: ST10)"

November 9, 2026
MEDLEAP PHARMA COMPANY LIMITED

■ Initiation of New Phase 2 Trial Aiming for an Additional Indication

MEDLEAP PHARMA COMPANY LIMITED (Head Office: Sendai City, Miyagi Prefecture; Representative Director: Yuichi Kobayashi; hereinafter referred to as "MEDLEAP PHARMA") announces that it has newly initiated a Phase 2 clinical trial in Japan targeting patients with pulmonary hypertension associated with chronic pulmonary disease, for its novel drug candidate "Ferric Maltol (Development Code: ST10)," which is under development as a treatment for Pulmonary Arterial Hypertension (PAH). This trial will be conducted as an exploratory study toward a Phase 3 trial.

■ Comment from Dr. Koichiro Tatsumi, Medical Expert and Professor Emeritus, Department of Respiratory Medicine, School of Medicine, Chiba University

～Conducting a Clinical Trial of the Novel Compound "Ferric Maltol" Aiming to Improve Cardiac Function and Exercise Tolerance in Pulmonary Hypertension Associated with Chronic Pulmonary Disease ～Toward Building Evidence Originating from Japan and Creating New Treatment Options～

In pulmonary hypertension associated with chronic pulmonary diseases such as chronic obstructive pulmonary disease (COPD) and interstitial lung disease (ILD), a decrease in hemoglobin (Hb) levels is observed in many patients. This is not limited to anemic symptoms but is strongly associated with decreased cardiac function and exercise tolerance, and adverse effects on pulmonary vascular lesions and right heart function have also been suggested. Therefore, appropriate correction and maintenance of Hb levels have become an important issue in the long-term management of this disease.

For this patient group, long-term and continuous iron supplementation is essential; however, existing oral iron preparations have presented challenges that hinder continuation of treatment, such as gastrointestinal side effects and insufficient absorption. For this reason, the emergence of a new iron supplementation therapy combining high tolerability and good absorption has been desired.

"Ferric Maltol," a novel compound that overcomes these challenges, enables stable, long-term iron supplementation, and is therefore highly expected to serve as a new therapeutic approach for pulmonary hypertension associated with chronic pulmonary disease. The implementation of this clinical trial is expected to further expand treatment options and generate high-quality evidence originating from Japan.

■ Trial Overview

- **Trial Name**: Exploratory Phase 2 Trial to Evaluate the Efficacy and Safety of Ferric Maltol (ST10) in Patients with Pulmonary Hypertension Associated with Chronic Pulmonary Disease
- **Target Disease**: Pulmonary Hypertension Associated with Chronic Pulmonary Disease
- **Trial Design**: Multicenter, Randomized, Placebo-Controlled, Double-Blind
- **Number of Subjects**: Approximately 16 (planned)

- Primary Endpoint: Change from baseline in 6-minute walk distance at 12 weeks after administration
- Secondary Endpoints: Cardiac function-related efficacy parameters, safety, tolerability, etc.
- Countries Conducting the Trial: Japan

■ About "Ferric Maltol (Development Code: ST10)"

This drug, Ferric Maltol (ST10), has been developed and is already marketed in Europe and the United States as a treatment for iron deficiency. Ferric Maltol is a clearly defined novel covalent complex. This binding mode suppresses the formation of free iron, thereby reducing gastrointestinal irritation, and is also expected to improve vascular remodeling and tissue damage, as well as pulmonary hemodynamics and prognosis in patients with pulmonary hypertension. In addition, it is a novel iron compound that achieves efficient and reliable absorption, and has been recognized by the U.S. FDA as a New Chemical Entity (NCE). Iron (Fe^{3+}) and maltol form a chemically stable complex, which exists in this complex form within the gastrointestinal lumen. At the site of intestinal absorption, this complex dissociates into iron and maltol for the first time, thereby reducing the direct impact on the gastrointestinal tract caused by free iron.

For these reasons, Ferric Maltol can be administered on an empty stomach, and is a novel oral iron preparation designed to reduce gastrointestinal side effects, improve absorption efficiency, optimize dosage, and reduce iron-related toxicity through optimal blood concentration.

MEDLEAP PHARMA positions this drug as a core pipeline asset in the pulmonary hypertension field and is advancing its clinical plan with a view toward global development expansion.

■ Future Development Plan

Based on the results of this trial, MEDLEAP PHARMA plans to conduct a Phase 3 trial (Pivotal Study) and to proceed to preparations for regulatory approval application and market launch from 2030 onward.

Through this drug, MEDLEAP PHARMA aims to strengthen its mid- to long-term revenue base and enhance corporate value.

■ About MEDLEAP PHARMA COMPANY LIMITED

MEDLEAP PHARMA COMPANY LIMITED has adopted the mission of "Bringing innovation to the future of Japanese healthcare through the creation of original pharmaceuticals," and contributes to resolving Japan's drug loss issue through its business of supporting the introduction of unapproved drugs, delivering a healthy future to patients and their families.

Through collaboration with research institutions and companies both in Japan and overseas, MEDLEAP PHARMA is promoting the creation of competitive new drugs.

- Head Office Location: 3-3-1 Yaotome, Izumi-ku, Sendai City, Miyagi Prefecture, 981-3112
- Representative: Representative Director Yuichi Kobayashi
- Established: September 2025
- Business Description: Research, development, manufacturing, and sale of pharmaceuticals

■ Regarding Future Outlook

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

■ Contact Information Regarding This Matter

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