Distribution Rights Agreement for TYVASO DPI™, a Treatment for Pulmonary Arterial Hypertension and Pulmonary Hypertension Associated with Interstitial Lung Disease, in Japan

This material is an English translation of the press release issued on October 31, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

October 31, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Headquarters: Shinjuku-ku, Tokyo, President: Naoyuki Mochida, hereinafter called "Mochida") announces today that Mochida and United Therapeutics Corporation (Headquarters: Silver Spring, MD, CEO: Martine Rothblatt, hereinafter called "United Therapeutics") have signed an agreement for the exclusive distribution of TYVASO DPI™, a treatment for pulmonary arterial hypertension (PAH; WHO Group 1) and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve the ability to exercise, in Japan. Under this agreement, Mochida will be responsible for obtaining marketing authorization of TYVASO DPI™ and conducting necessary local clinical studies in Japan.

TYVASO DPITM (treprostinil) Inhalation Powder consists of single-dose plastic cartridges filled with a dry powder containing treprostinil as the active ingredient, which is intended for administration by oral inhalation using the TYVASO DPI Inhaler. In the United States, the product has been marketed by United Therapeutics since 2022 under the brand name TYVASO DPITM (treprostinil) Inhalation Powder.

PAH and PH-ILD are rare diseases where patients experience high pulmonary arterial pressure accompanied by symptoms such as dyspnea on exertion, fatigue, palpitations, and dizziness. This disease progresses over time and can lead to heart failure.

Since 2014, Mochida has been marketing TREPROST® (treprostinil) Injection, a treatment for PAH in Japan, also under an exclusive distribution agreement with United Therapeutics. In 2023, Mochida launched sales of TREPROST® (treprostinil) Inhalation Solution in Japan for the treatment of PAH, and in 2024, the additional indication for PH-ILD was approved by the MHLW in Japan. Mochida believes that TYVASO DPITM will provide additional therapeutic options for patients with PAH and PH-ILD with its convenience to use and portability.





TYVASO and TREPROST are registered trademarks of United Therapeutics Corporation. TYVASO DPI is a trademark of United Therapeutics Corporation.