

Mochida Filed an Application for Approval of an Additional Indication for TREPROST® Inhalation Solution for Pulmonary Hypertension Associated with Interstitial Lung Disease or Combined Pulmonary Fibrosis and Emphysema, in Japan

This material is an English translation of the press release to be issued on December 25, 2023 in Japanese, and the Japanese release is given priority regarding content and interpretation.

December 25, 2023

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter : Mochida) announced that Mochida filed an application for approval of an additional indication for TREPROST® Inhalation Solution 1.74mg (generic name: treprostinil; development code: MD-711) for pulmonary hypertension (PH) associated with interstitial lung disease (ILD) or combined pulmonary fibrosis and emphysema (CPFE), to the Japanese Ministry of Health, Labour and Welfare (MHLW).

PH is a general term for pathological conditions in which elevated pulmonary artery pressure is observed. PH associated with ILD or CPFE, is classified into the third group of PH due to pulmonary disease and/or hypoxia among the five groups of PH based on the causes and pathologies. Due to the poor prognosis, early therapeutic intervention is necessary, but there are no drugs approved for the indication of this disease in Japan.

Mochida obtained the distribution rights for the product from United Therapeutics Corporation in 2017 and has been marketing it in Japan as a treatment for pulmonary arterial hypertension (PAH) since early 2023. In the United States, the product has been marketed as TYVASO® for the indication of PAH since 2009, and the indication for PH associated with ILD (including CPFE) was added in 2021. Treprostinil has been designated as an orphan drug by the MHLW for the expected indication of PH associated with ILD (including CPFE).

As a company in the life and healthcare business, Mochida is committed to meeting unmet medical and healthcare needs. Mochida will continue to make every effort to obtain approval so that it can contribute to improving the quality of life of patients with PH.

TYVASO and TREPROST are registered trademarks of United Therapeutics Corporation.