Mochida Obtained Approval for an Additional Indication of TREPROST® Inhalation Solution for Pulmonary Hypertension Associated with Interstitial Lung Disease in Japan

This material is an English translation of the press release to be issued on September 24, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

September 24, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that Mochida has obtained approval for an additional indication of TREPROST® Inhalation Solution 1.74mg (generic name: treprostinil; development code: MD-711) for the treatment of pulmonary hypertension (PH) associated with interstitial lung disease (ILD) on September 24, 2024.

PH is a general term for pathological conditions in which elevated pulmonary artery pressure is observed. PH associated with ILD 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 until now there have been no drugs indicated for 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 was added in 2021. Treprostinil has been designated as an orphan drug by the Ministry of Health, Labour and Welfare for the indication of PH associated with ILD (including combined pulmonary fibrosis and emphysema) in Japan.

As a company in the life and healthcare business, Mochida is committed to meeting unmet medical and healthcare needs. Mochida expects that the product will contribute to improving the quality of life of patients with PH associated with ILD.

[References]

Summary of the approval

The underlined part has been added.

Brand Name	:	TREPROST® Inhalation Solution 1.74mg
Generic Name	:	Treprostinil
Ingredients and Contents	:	Sterile solution for oral inhalation 1.74 mg treprostinil per ampule
Indications	:	Pulmonary arterial hypertension Pulmonary hypertension associated with interstitial lung disease
Dosage and Administration	:	(Pulmonary arterial hypertension) Administer in 4 separate treatment sessions each day. Initial dosage: 3 breaths (18 μg of treprostinil) per treatment session. Dosage should be increased by an additional 3 breaths per treatment session at approximately 7 days or more intervals, if tolerated, up to the target dose of 9 breaths (54 μg of treprostinil) per treatment session. If there are concerns about the tolerability of increasing the dose by 3 breaths, the dose may be increased by 1 breath or 2. If not tolerated, the dose should be reduced and the minimum dose should be 1 breath per treatment session. (Pulmonary hypertension associated with interstitial lung disease) Administer in 4 separate treatment sessions each day. Initial dosage: 3 breaths (18 μg of treprostinil) per treatment session. Dosage should be increased by an additional 1 breath per treatment session at approximately 3 days or more intervals, if tolerated, up to the target dose of 12 breaths (72 μg of treprostinil) per treatment session. If not tolerated, the dose should be reduced and the minimum dose should be 1 breath per treatment session.
Manufacturer / Distributor	:	Mochida Pharmaceutical Co., Ltd.