Mochida Obtains Marketing Approval for Treprost® Inhalation Solution, a Treatment for Pulmonary Arterial Hypertension, in Japan

This material is an English translation of the press release to be issued on December 23, 2022 in Japanese, and the Japanese release is given priority regarding content and interpretation.

December 23, 2022

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter : Mochida) announced that Mochida obtained marketing approval for “Treprost® Inhalation Solution 1.74mg” (generic name: treprostinil; development code: MD-711), a treatment for pulmonary arterial hypertension (PAH) in Japan on December 23.

The product is an inhaled medicine, which contains a synthetic prostacyclin analog, treprostinil, as the active ingredient. Mochida has been developing it in Japan under an agreement with United Therapeutics Corporation since 2017. This product has been marketed in the United States as Tyvaso® (treprostinil) Inhalation Solution since 2009. The product is non-invasive and can be self-administered by patients using a dedicated lightweight portable nebulizer.

PAH is characterized by elevated pulmonary artery pressure caused by narrowing and hardening of the pulmonary arteries that carry blood from the heart to the lungs. It is an orphan refractory disease accompanied by symptoms such as dyspnea, fatiguability, palpitations and dizziness on exertion and the disease causes heart failure as it progresses.

Mochida has been distributing Treprost®, a treprostinil injection product for PAH, since 2014. In the treatment of PAH, injections, oral medications and inhalants are used properly depending on the severity of the disease. Mochida believes that Treprost® Inhalation Solution will provide additional therapeutic options for patients with PAH and contribute to improvement of their quality of life.

[References]

Summary of the marketing approval

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
Dosage and Administration	:	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.
Approval Date	:	December 23, 2022

TYVASO is a registered trademark of United Therapeutics Corporation.