Mochida files New Drug Application for MD-711, a Treatment for Pulmonary Arterial Hypertension, in Japan

This material is an English translation of the press release to be issued on February 4, 2022 in Japanese, and the Japanese release is given priority regarding content and interpretation.

February 4, 2022

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter : Mochida) announced that the company filed a new drug application (NDA) for MD-711, a treatment for pulmonary arterial hypertension (PAH), with the Japanese Ministry of Health, Labour and Welfare (MHLW).

MD-711 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.

PAH is characterized by elevated pulmonary artery pressure caused by certain conditions. It is an orphan refractory disease accompanied by symptoms such as dyspnea, fatiguability, palpitations and dizziness on exertion and causes heart failure as it progresses. PAH is a designated intractable disease in Japan, and the number of PAH patients who were registered as designated intractable diseases patients is 3,934 in 2019.

Mochida has been distributing Treprost®, a treprostinil injection product for PAH, under an agreement with United Therapeutics, since Mochida obtained the marketing authorization for this product in 2014. Mochida believes that MD-711 will provide additional therapeutic options for patients with PAH and contribute to improvement of their QOL.

Mochida is also conducting another clinical study for MD-711 as a treatment for pulmonary hypertension associated with interstitial lung disease (including combined pulmonary fibrosis and emphysema : CPFE), which has been designated as an orphan drug by MHLW in December 2021.