NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

April 16, 2024

Nippon Shinyaku Submitted Additional Application of Uptravi® tablets 0.2 mg and 0.4 mg for the Treatment of Pediatric PAH and NDA of Pediatric 0.05 mg formulation to MHLW

Kyoto, Japan, April 16, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the company submitted additional application of Uptravi® tablets 0.2 mg and 0.4 mg (Generic name; Selexipag) for the treatment of pediatric pulmonary arterial hypertension (PAH), as well as a new drug application for the pediatric 0.05 mg formulation to the Ministry of Health, Labor and Welfare (MHLW) in Japan. Selexipag was originally discovered and synthesized by Nippon Shinyaku Co., Ltd. and Uptravi® tablets 0.2 mg and 0.4 mg have obtained indications for adult PAH and adult Chronic Thromboembolic Pulmonary Hypertension.

PAH is a disease with a poor prognosis characterized by abnormally high blood pressure in the pulmonary artery. It is classified into idiopathic PAH, heritable PAH and PAH associated with various diseases such as connective tissue disease and congenital heart disease. Because the disease pathology of PAH is similar between in pediatric and in adult, combination therapy of prostacyclin pathway drug, endothelin receptor antagonist and phosphodiesterase-5 inhibitor, are also recommended for pediatric PAH patients. However, treatment options for pediatric PAH are limited in Japan. Particularly, in the case of prostacyclin pathway drug, only injectable requiring continuous intravenous infusion is available. Therefore, there has been a desire for oral formulations of prostacyclin pathway drug.

Uptravi® is an oral prostacyclin receptor (IP receptor) agonist with high selectivity for the IP receptor among prostacyclin pathway drugs. Uptravi® is believed to reduce pulmonary arterial pressure by binding to the IP receptors on vascular smooth muscle cells and increasing cAMP production, thereby leading to vasodilation and inhibition of vascular smooth muscle proliferation.

Nippon Shinyaku will continue to make further efforts to deliver this drug and its pediatric formulation as a new treatment option to pediatric patients suffering from PAH as soon as possible.

About Endothelin Receptor Antagonist (ERA)

Endothelin is a potent endogenous substance with strong vasoconstriction and vascular smooth muscle proliferation, and is abundant in the bodies of patients with PAH. ERAs are drugs that bind to endothelin receptors, inhibiting the actions of endothelin.

About Phosphodiesterase-5 (PDE5) inhibitor

PDE5 is abundantly distributed in the blood vessels of the lungs, and it degrades cGMP, an endogenous substance that dilates blood vessels. PDE5 inhibitors inhibit the degrades of cGMP by PDE5, enhancing the function of cGMP and dilating blood vessels in the lungs.

Contact

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