NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

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Johnson & Johnson Obtains Approval for YUVANCI® Combination Tablet for the Treatment of Pulmonary Arterial Hypertension

Kyoto, Japan, September 24, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that Johnson & Johnson (Janssen Pharmaceutical K.K.; Headquarters, Chiyoda, Tokyo; President, Shuhei Sekiguchi) has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) for YUVANCI®- single-tablet combination of macitentan, an endothelin receptor antagonist, and tadalafil, a phosphodiesterase 5 inhibitor - for the treatment of pulmonary arterial hypertension (PAH). In Japan, commercial activities of YUVANCI® with healthcare professionals will be conducted in collaboration with Johnson & Johnson.

PAH is characterized by the constriction of small pulmonary arteries and elevated blood pressure in pulmonary circulation, and is designated as an intractable disease by the Ministry of Health, Labor and Welfare[1]. Three types of pulmonary vasodilators, prostacyclines, endothelin receptor antagonists, and phosphodiesterase 5 inhibitors, are commonly used in the treatment of PAH, and combination therapy with two or three of these is also used.

YUVANCI® is a combination of macitentan and tadalafil, and individually, macitentan reduces the risk of clinical worsening events and hospitalization[2], and tadalafil improves exercise ability[3].

This approval is based on results from the Pivotal Phase IIIA DUE Study, in which YUVANCI® demonstrated greater reduction in Pulmonary Vascular Resistance (PVR) after 16 weeks versus tadalafil or macitentan monotherapy[4]. The safety profile of YUVANCI® was consistent with that of macitentan and tadalafil.

Nippon Shinyaku is focusing on the field of intractable, rare disorders, and PAH is one of them. Our products in PAH include Uptravi® (selexipag), Opsumit® (macitentan), and Adcirca® (tadalafil), and with the addition of YUVANCI®, we believe it will make a further contribution to the treatment of PAH.

About the A DUE Study (NCT03904693)

The A DUE study[4] was a double-blind, randomized, active-controlled, multi-center, adaptive, parallel-group study designed to compare the efficacy and safety of YUVANCI® to macitentan and tadalafil monotherapies in adult patients with PAH (WHO FC II or III). The three-arm trial enrolled patients from across 76 sites in 16 countries/territories worldwide who were treatment-naïve or on a stable dose of an endothelin receptor antagonist (ERA), or a phosphodiesterase 5 (PDE5) inhibitor, for at least three months. The primary endpoint was change from baseline in PVR at the end of double-blind treatment at 16 weeks and was considered met if macitentan and tadalafil fixed-dose combination (FDC) treatment was superior to both monotherapies. Following the treatment period, patients transitioned to the open-label treatment period for 24 months.

References

1. Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/171
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3. Galiè N, Brundage BH, Ghofrani HA, Oudiz RJ, Simonneau G, Safdar Z, et al. Tadalafil therapy for pulmonary arterial hypertension. Circulation 2009;119:2894–2903.
4. Grünig E, et al. JACC. 2024; 83(4): 473-484. DOI:10.1016/j.jacc.2023.10.045.

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