NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

November 20, 2024

YUVANCI® Combination Tablets for the Treatment of Pulmonary Arterial Hypertension: Start of co-promotion activities with Johnson & Johnson

Kyoto, Japan, November 20, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that it has started co-promotion activities with Johnson & Johnson (Janssen Pharmaceutical K.K.; Headquarters, Chiyoda, Tokyo; President, Shuhei Sekiguchi) for YUVANCI® Combination Tablets for the treatment of pulmonary arterial hypertension (PAH), which was launched by Johnson & Johnson today in Japan.

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 MHLW[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 single-tablet combination of macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, and approved based on results from the Pivotal Phase III A DUE Study[2]. YUVANCI® has the potential to optimise disease management and reduce patient pill burden by combining macitentan and tadalafil, each with established efficacy and safety profiles, into one tablet.

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 Product

Product name	Yuvanci® Combination Tablets
Generic name	Macitentan / tadalafil
Indication	Pulmonary arterial hypertension (PAH)
Dosage and Administration	One tablet (macitentan 10mg, tadalafil 40mg) taken orally once daily for adult patients
Packaging	30 tablets (3 sheets x 10 tablets)
Pricing	JPY 13,334.90 / tablet
Date of approval	September 24, 2024
Date of NHI reimbursement price listing	November 20, 2024
Date of launch	November 20, 2024
Marketing Authorization Holder	Janssen Pharmaceutical K.K.
Co-promotion partner	Nippon Shinyaku Co., Ltd.

About the A DUE Study (NCT03904693)

The A DUE study 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
2. Grünig E, et al. JACC. 2024; 83(4): 473-484. DOI:10.1016/j.jacc.2023.10.045.

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