NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

December 22, 2025

Johnson & Johnson Obtains Approval of OPSUMIT® for the Treatment of Pediatric Patients with Pulmonary Arterial Hypertension in Japan

Kyoto, Japan, December 22, 2025 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto; President: Toru Nakai) announced today that Johnson & Johnson ("J&J") has obtained approval from the Japan's Ministry of Health, Labor and Welfare (MHLW) for Opsumit® tablets 10 mg (weight >= 50kg), an endothelin receptor antagonist, for the additional indication of pediatric pulmonary arterial hypertension (PAH), as well as for a new drug application for Opsumit® Pediatric Dispersible Tablets in 1.0 mg and 2.5 mg (age >=3 Months).

The approval is supported by data from the global 67896062PAH1010 study (PAH1010) and TOMORROW studies, and local 67896062PAH3001 study (PAH3001) conducted by J&J.
Nippon Shinyaku will conduct information activities for Opsumit® in collaboration with J&J.

PAH is a specific form of PH that causes the walls of the pulmonary arteries (blood vessels leading from the right side of the heart to the lungs) to become thick and stiff, narrowing the space for blood to flow, and causing an increased blood pressure to develop within the lungs. PAH is a serious, progressive disease with a variety of etiologies, and has a major impact on patients' functioning, as well as their physical, psychological and social wellbeing. There is currently no cure for PH and it is often fatal[1-3]. However, the last decade has seen significant advances in the understanding of the pathophysiology of PAH, transforming the prognosis for PAH patients from symptomatic improvements in exercise tolerance 10 years ago, to delayed disease progression today.

Nippon Shinyaku is focusing on the field of intractable, rare disorders, and PAH is one of them. Currently, for adult PAH, we offer a portfolio of products including Uptravi® (selexipag), Opsumit® (macitentan), Adcirca® (tadalafil), and Uvanshi® Combination Tablets (macitentan/tadalafil). For pediatric PAH, in addition to Uptravi®, we believe that the additional indication for Opsumit® will further contribute to the treatment of PAH.

About PAH1010 study (NCT05433675)

A single-center, open-label, single-dose randomized, 2-way crossover Phase I study in health adult participants to assess the bioequivalence of OPSUMIT® tablet 10mg and its pediatric dispersible tablet in fasted conditions.

About TOMORROW study (NCT02932410)

The TOMORROW study is a multicenter, open-label, randomized, single-arm-extension Phase III trial evaluating the pharmacokinetics (PK), safety, and efficacy of OPSUMIT® versus standard of care (SoC) in pediatric PAH patients.

About PAH3001 study (NCT05167825)

A multicenter, open-label Phase III study to access the efficacy, safety and PK of OPSUMIT® in Japanese patients (>=3 Months to <15 Years) with PAH.

References

1. Vachiéry JL and Gaine S. Eur Respir Rev 2012; 21:313-20.
2. Galiè N, et al. Eur Heart J 2016; 37:67–119.
3. Hoeper MG, Gibbs SR. Eur Respir Rev 2014; 23:450–7.

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