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Insmed reports 12-month TPIP data in pulmonary arterial hypertension

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The open-label extension data showed sustained improvements across functional, biomarker and risk-status measures in patients with PAH.

Insmed has reported positive 12-month data from the ongoing open-label extension study of treprostinil palmitil inhalation powder in patients with pulmonary arterial hypertension.

TPIP is being evaluated as a once-daily inhaled prostanoid therapy. The open-label extension study is assessing long-term safety, tolerability and effectiveness over 24 months in patients who completed earlier TPIP PAH studies.

Pulmonary arterial hypertension remains a progressive and serious disease marked by increased pressure in the pulmonary arteries, reduced exercise capacity and risk of clinical worsening. Treatment often requires chronic therapy, and administration burden can affect adherence and patient quality of life.

At Month 12, patients receiving TPIP showed sustained improvements across secondary efficacy endpoints including six-minute walk distance, NT-proBNP concentration, WHO Functional Class and REVEAL Lite 2.0 risk score.

Mean six-minute walk distance improved by 55.7 metres in the TPIP Continued group and 54.1 metres in the Placebo Crossed group. NT-proBNP concentration was reduced by approximately 60 per cent in both groups.

WHO Functional Class I or II was achieved in 78.3 per cent of patients in the TPIP Continued group and 80.6 per cent in the Placebo Crossed group. More than 25 per cent of patients across both groups achieved WHO Functional Class I.

Approximately 65 per cent of all patients achieved Refined Low Risk status by REVEAL Lite 2.0, a category associated with lower estimated mortality and clinical worsening risk. Insmed said the data, together with once-daily inhaled administration, reinforce TPIP’s potential in PAH therapy.

The safety data showed that once-daily TPIP was generally well tolerated with no newly identified safety signals through Month 12. Doses up to 1,280 µg once daily were permitted in the extension study.

The development is commercially relevant because existing PAH treatment can involve complex administration requirements. A once-daily inhaled prostanoid option could be meaningful if Phase 3 data confirm efficacy, safety and tolerability.

Insmed is advancing the Phase 3 PALM-PAH study. The open-label extension data are supportive, but the therapy remains investigational and will require confirmatory evidence from controlled late-stage studies.