



SPHERIC-1OE

(Sildenafil nelle Pneumopatie ostruttive cHE pResentano Ipertensione Polmonare Cronica – Open Extension)

SUMMARY

The open extension protocol aimed to keep patients on treatment until the conclusion of the double-blind phase II study.

Following the conclusion of the "core" study and having no pivotal phase 3 studies planned, the decision was made to open the blind and to continue the treatment only in patients who took the experimental drug during the blinded study in the regimen of compassionate use, with medication provided free of charge by the sponsor. Therefore no data were collected and the OE study was stopped. No serious adverse events were reported during observation of patients treated in compassionate use.

Responsabile Scientifico e Centro Coordinatore dello Studio

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