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EREMISS trial: A double-blind placebo (PBO)-controlled randomised trial assessing efficacy/safety of regorafenib (REGO) as maintenance therapy after 1st line doxorubicin-based chemotherapy in advanced soft-tissue sarcoma (ASTS) patients (pts)

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Background

REGO is a multikinase inhibitor showing efficacy as salvage treatment in non-adipocytic ASTS (Mir et al. Lancet Oncol. 2016). We explore here the role of REGO as maintenance therapy after 1st line treatment.

Methods

EREMISS (NCT03793361) was a double-blind, PBO-controlled, comparative, randomised phase 2 trial assessing the activity and safety of REGO (120 mg/d, 3 weeks / 4) in pts with non-adipocytic ASTS, who had stable disease (SD) or partial tumour response (PR) after 6 cycles of doxorubicin-based chemotherapy as 1st line treatment. There was no planned cross-over. The primary endpoint was progression-free survival (PFS) according to RECIST 1.1 evaluated by blinded independent, central review (BICR). Based on the following assumptions: PFS(PBO)=4 mo, expected PFS(REGO)=7 mo, HR=0.57, 1-sided α=.05 and β=.10, 110 events (PD), 126 pts were required (see 1731TiP, ESMO 2019).

Results

The study population consisted of 126 pts (PBO: 62, REGO: 64) enrolled in 17 centres from May 2019 to Nov 2022, 55% female, median age=58 years (range, 18-85). The most common subtype was leiomyosarcoma (59%). All pts had previously received 6 cycles of doxorubicin-based chemotherapy (+ DTIC in 24%, IFO in 14%); PR in 30%, SD in 70%. Median follow-up was 27 mo. Median duration of treatment was 3.4 (PBO) vs 4.3 mo (REGO). The primary objective was assessable in 122 pts (109 events). Median PFS by BICR was 3.5 (PBO) vs 5.6 mo (REGO) (HR=0.51; p=.001). According to investigator assessment, median PFS was 3.6 vs 6.8 mo (HR=0.56, p=.002). Median OS was 21.0 vs 27.6 mo (HR=0.82; p=.41). The rate of Gr≥3 AEs was 11% (PBO) vs 66% (REGO). Toxicity led to permanent treatment discontinuation in 18/64 REGO pts (28%), 0/62 PBO. The most common Gr≥3 clinical AEs in REGO arm were asthenia (9%), arterial hypertension (8%) and rash (8%).

Conclusions

This trial met its primary objective, REGO significantly delays disease progression after doxorubicin-based 1st line treatment in ASTS. This was associated with a non-significant trend of OS improvement. This benefit must be balanced with the occurrence of AEs.

Clinical trial identification

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Legal entity responsible for the study

Centre Oscar Lambret.

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Disclosure

All authors have declared no conflicts of interest.