Randomized, open-label, multicenter, phase III study of eribulin versus dacarbazine in patients (pts) with leiomyosarcoma (LMS) and adipocytic sarcoma (ADI).

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Research Funding:

None

Background:

In a phase II study of pts with advanced soft tissue sarcoma, 32% and 47% of pts with LMS and ADI respectively, treated with the microtubule dynamics inhibitor eribulin achieved progression-free survival (PFS) at the 12 wk timepoint (Schöffski et al. *Lancet Oncol.* 2011; NCT00413192). Based on these findings, this phase III study (NCT01327885) compared overall survival (OS) in pts with advanced LMS and ADI treated with eribulin or dacarbazine.

Methods:

Pts aged ≥ 18 yrs with advanced high/intermediate grade LMS or dedifferentiated, myxoid, round cell or pleomorphic variants of ADI incurable by surgery and/or radiotherapy were enrolled. Pts had ECOG status ≤ 2 and had received ≥ 2 standard systemic treatment regimens including an anthracycline. Pts were randomized 1:1 to eribulin (1.4 mg/m^2 , IV on D1 and D8) or dacarbazine ($850\text{--}1200 \text{ mg/m}^2$, IV on D1) every 21 days until disease progression. Primary endpoint was OS. Secondary endpoints included PFS, PFS rate at Wk 12 and safety.

Results:

Overall, 452 pts (67% female; 79% < 65 yrs) were randomized (228 eribulin; 224 dacarbazine). Median OS for eribulin and dacarbazine was 13.5 and 11.5 months, respectively (HR = 0.768, 95% CI 0.618–0.954; $P=0.017$). PFS was 2.6 months in both arms (HR=0.877, 95% CI 0.710–1.085; $P=0.229$). PFS rate at Wk 12 was 33% and 29% for eribulin and dacarbazine, respectively. In eribulin and dacarbazine arms, respectively, 26% and 14% of pts required dose reductions and 8% and 5% discontinued due to treatment-emergent adverse events (TEAEs). TEAEs were more frequent in eribulin than dacarbazine arm, including neutropenia (44% vs 24%), pyrexia (28% vs 14%), peripheral sensory neuropathy (20% vs 4%) and alopecia (35% vs. 3%); as were TEAEs of grade 3 (63% vs 53%), grade 4 (26% vs 20%), and fatal TEAEs (4% vs 1%). Thrombocytopenia was more frequent in dacarbazine than eribulin arm (28% vs 6%).

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Conclusions:

This phase III trial of eribulin met its primary objective of OS benefit in pretreated pts with advanced LMS or ADI. Eribulin had a toxicity profile consistent with prior experience, with no

unexpected or new safety findings. Funding Source: Eisai Inc. Clinical trial information: [NCT01327885](https://clinicaltrials.gov/ct2/show/study/NCT01327885)

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