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ASPEN-04: A randomized phase II study of evorpacept in combination with pembrolizumab and chemotherapy in patients with recurrent, unresectable or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)

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Background

Evorpacept (evo) is a high affinity, CD47-blocking, myeloid checkpoint inhibitor (CPI) with an inactive Fc region designed to safely combine with and enhance standard anticancer regimens by activating both innate and adaptive immune responses. Evo is being evaluated in patients with advanced malignancies, including R/M HNSCC.

Methods

ASPEN-04 is a randomized, open-label Phase 2 study evaluating evo in combination with P and C [5FU + either carboplatin or cisplatin] in patients with previously untreated, R/M HNSCC. An initial safety lead-in preceded the randomized part of the study. 165 patients were randomized 2:1 to evo (45 mg/kg Q3W) in combination with PC or PC alone. Minimization factors included: geographic region, PD-L1 combined positive score (CPS), HPV (p16) status, tobacco habits, and ECOG performance status. The primary endpoint was objective response rate (ORR) by blinded independent central review (BICR) compared to historical control ORR of 36.4% (Burtness et al., 2019).

Results

In the intention-to-treat (ITT) population, confirmed ORR for evo + PC (N=110) was 37.3% (95% confidence interval (CI), 28.2-47.0%) compared to 36.4% for historical control and 45.5% (95% CI, 32.0-59.4%) for PC (N=55). The difference between ORRs for evo + PC and historical PC was not statistically significant (p=0.43). Evo + PC was generally well-tolerated with a safety profile consistent with previous clinical experience. DOR, PFS, OS, and the results of exploratory analyses will be presented at the meeting.

Conclusions

The addition of evo to PC did not meet the primary endpoint of improved ORR in R/M HNSCC as compared to historical control. While additional exploratory analyses are ongoing, study results do not support further development of evo in combination with PC in R/M HNSCC.

Clinical trial identification

NCT04675333.

Legal entity responsible for the study

ALX Oncology.

Funding

ALX Oncology.

Disclosure

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