Abstract #366992: Penpulimab plus anlotinib in patients with recurrent or metastatic head and neck squamous cell carcinoma after the failure of first-line platinum-based chemotherapy: a single-arm, multicenter, phase 2 study

Authors: Changgong Zhang[1], Liying Gao[2], Youxin Tian[2], Chunmei Bai[3], Jianhua Chen[4], Jun Wang[2], Xingya Li[5], Yan Sun[6], Haichuan Su[7], Zhigang Liu[8], Yuankai Shi[1].
[1]Cancer Hospital Chinese Academy of Medical Sciences, [2]Gansu Provincial Cancer Hospital, [3]Peking Union Medical College Hospital, [4]Hunan Cancer Hospital, [5]First Affiliated Hospital of Zhengzhou University, [6]Beijing Cancer Hospital, [7]Tangdu Hospital; [8]The Cancer center of the Fifth Affiliated Hospital of Sun Yat-sen University

Background

- Penpulimab is a novel human immunoglobulin G1 (IgG1) anti-programmed cell death-1 (PD-1) antibody.
- ALTN-AK105-II-01 (NCT04203719) is a single-arm, multi-cohort, multicenter phase 2 study to explore the efficacy and safety of penpulimab plus anlotinib, a multikinase inhibitor, in the treatment of various advanced cancers.
- Here we report the results of the cohort 1 for patients (pts) with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC).

Methods

Key Eligibility Criteria
- Histologically confirmed R/M HNSCC
- Failed prior platinum based chemotherapy
- ≥18 years, ECOG PS 0-1
- ≥ 1 measurable lesion（RECIST 1.1）
- previous anti-angiogenic agents or immune checkpoint inhibitors naïve

Anlotinib 12mg, d1~14, q3w +Penpulimab 200mg, d1, q3w → **Until PD or Unacceptable AE** → **Primary endpoints:** ORR **Secondary endpoints:** DCR, DoR, PFS, OS, Safety

- From June, 2020 to November, 2021, 38 pts were enrolled in 8 centers in China.
- Baseline characteristics were shown in Table.1

Results

- As of January 6, 2022 (data cut-off),The study met its primary endpoint that 13 pts achieved partial response (PR) and the ORR (confirmed at least 4 weeks after initial response) was 34.21%.
- After a median follow-up of 6.96 months (95%CI: 4.40, 8.80). PFS events were observed in 17 pts and the median PFS was 8.35 months (95%CI: 5.45, 13.11). For pts with tumor response, the median DoR was not reached (95% CI: 2.37, NE).
- Treatment-related adverse events (TRAEs) occurred in 89.47% pts, TRAE of grade 3 or above occurred in 39.47% of pts. The most common TRAEs were hypertension (28.95%) and hypothyroidism (28.95%).

Figure 1. Waterfall plot of best change from baseline

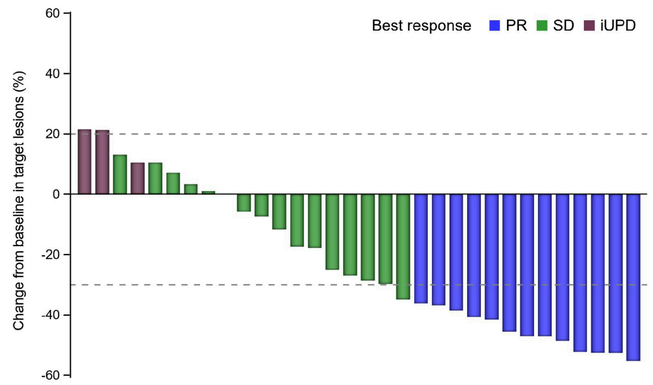


Table.2 Tumor response

	Overall (n=38)
CR , n(%)	0
PR, n(%)	13 (34.2)
SD, n(%)	16 (42.1)
iUPD, n(%)	3 (7.9)
NE, n(%)	6 (15.8)
ORR, %	34.2
DCR, %	76.3

Table.1 Baseline characteristics

Characteristics		n=38	Characteristics		n=38
Median age, years (range)		59 (34-80)	HPV-P16 status, n (%)	Positive	7 (18.4)
Gender, n (%)	Male	32 (84.2)		Negative	29 (76.3)
	Female	6 (15.8)		NA	2 (5.3)
Primary tumor site, n (%)	Oral cavity	15 (42.9)	Front-line Treatment, n (%)	Radiotherapy	28 (73.7)
	Larynx	10 (26.3)		Surgery	26 (68.4)
	Oropharynx	6 (15.8)		Chemotherapy	37 (97.4)
	Hypopharynx	4 (10.5)			

Figure 2. Swimmer plot of time to response and duration

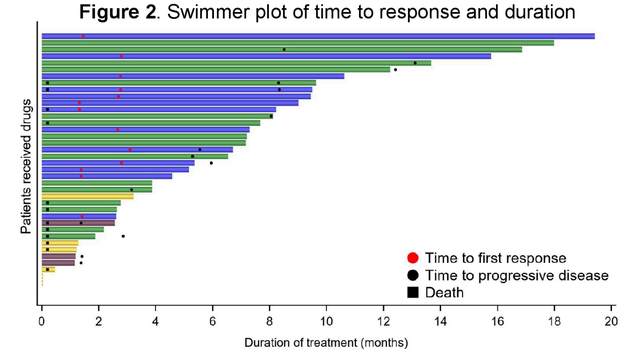
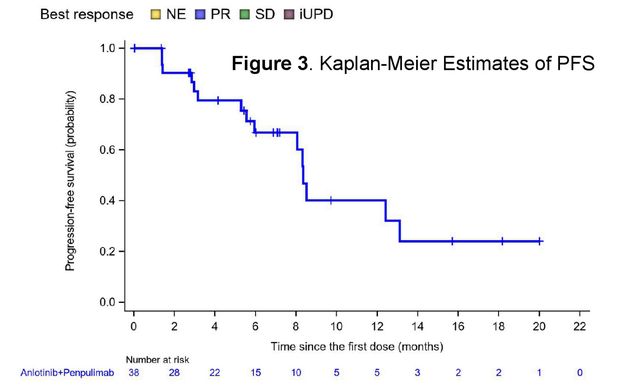


Figure 3. Kaplan-Meier Estimates of PFS



Conclusion

- The combination of penpulimab and anlotinib demonstrated promising efficacy and manageable toxicities in R/M HNSCC pts who failed standard first-line therapy.
- Further investigation is warranted.

All the authors declare no conflict of interests. * corresponding author:syuankaipumc@126.com