HEAD AND NECK CANCER, EXCLUDING THYROID

LBA35 Primary results from TACTI-003: A randomized phase IIb trial comparing eftilagimod alpha (soluble LAG-3) plus pembrolizumab versus pembrolizumab alone in first-line recurrent or metastatic head and neck squamous cell carcinoma with CPS ≥1

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Background: Eftilagimod alpha (E) is a soluble LAG-3 protein binding to a subset of MHC class II molecules to mediate antigen-presenting cell (APC) activation & T-cell (CD4/CD8) recruitment/activation. Previous results from a phase II study (NCT03625323) of E plus pembrolizumab (P) showed a promising objective response rate (ORR) in second line head and neck squamous cell carcinoma (HNSCC). An encouraging ORR of 35.5% was recently reported in first line (1L) recurrent or metastatic (R/M) HNSCC patients (pts) with CPS <1 treated with E+P (Cohort B; NCT04811027). We report primary results from the randomized Cohort A of TACTI-003 in 1L R/M HNSCC expressing PD-L1 (CPS ≥1).

Methods: Pts with measurable disease and CPS ≥1 were randomized to receive either E + P or P alone (E: 30 mg SC q2w for 24 weeks then q3w up to 2 yrs. P: 400 mg IV q6w up to 2 yrs). Primary endpoint (EP) was ORR by RECIST 1.1 in evaluable pts (≥1 post-baseline scan). Secondary EPs are ORR by iRECIST, duration of response, progression free survival, overall survival, safety & biomarkers. Imaging was done q9w & PD-L1 was prospectively assessed (22C3).

Results: 138 pts enrolled between Oct 2021—Oct 2023, resulting in 118 evaluable, 58 in E+P and 60 in P. Median age was 65 yrs (range: 38—87) & 74.6% were male. Primary tumor sites were hypopharynx (16.1%), larynx (17.8%), oral cavity (28.8%) & oropharynx (37.3%). ECOG PS was 0 in 43.2% & 1 in 56.8% of pts. 52.5% had CPS 1—19 and 47.5% had CPS ≥20. By data cutoff (Mar 11, 2024), 7 (E+P) vs 8 pts (P) experienced Grade ≥3 treatment emergent adverse reactions (TEARs). 3 pts per arm discontinued study treatment due to TEARs. E+P resulted in numerically higher ORR & DCR compared to P only in CPS ≥1 pts, with the largest differential in CPS ≥20.

Table: LBA35

Efficacy by RECIST 1.1	CPS ≥1		CPS 1—19		CPS ≥20	
	E+P, N=58	P, N=60	E+P, N=29	P, N=33	E+P, N=29	P, N=27
ORR, n (%)	19 (32.8)	16 (26.7)	10 (34.5)	11 (33.3)	9 (31.0)	5 (18.5)
DCR, n (%)	42 (72.4)	38 (63.3)	20 (69.0)	22 (67.7)	22 (75.9)	16 (59.3)

Conclusions: E+P is well tolerated with positive efficacy data and should be investigated further in HNSCC.

Clinical trial identification: IMP321-P022 (Sponsorcode); Keynote-PNC-34 (MSDcode); 2021-000055-39 (EudraCT); NCT04811027 (ClinicalTrials.gov).

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LBA36 A randomised phase II study to evaluate the efficacy and safety of androgen deprivation therapy (ADT) vs chemotherapy (CT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancers

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Background: Salivary duct (SDC) and adenocarcinomas (ADC) (ICDO-coding 8140/3) are aggressive cancers. AR expression is almost universal in SDC, rarely in ADC. The standard of care for recurrent, metastatic or unresectable (R/M/U) AR-expressing tumors is CT. To assess the value of ADT, an EORTC-led randomised phase II study was launched.

Methods: Patients (pts) with untreated R/M/U AR expressing SDC and ADC (cohort A) were randomised to receive CT (cisplatin 75 mg/m2 + doxorubicin 60 mg/m2 or carboplatin AUC 5 + paclitaxel 175 mg/m2 q3 weeks for a maximum of 6 cycles) or ADT (bicalutamide 50 mg once daily + triptorelin 3.75 mg q 28 days until progressive disease (PD)). A second single-arm cohort (B) received ADT until PD, and it included pretreated pts. Histology was centrally reviewed. IHC AR staining of ≥70 % was required. Primary objectives were to show superiority of progression free survival (PFS) of ADT over CT in cohort A, to describe overall response rate (ORR) in cohort B. Translational studies included HER2 and AR regulation mechanisms. A total of 89 pts were enrolled: 60 in cohort A (29 in ADT and 31 in CT) and 29 in cohort B. Cohort B included 54 pts (25 switched from cohort A upon PD). The majority were male (93%). Median age was 65 (35-80y).

Results: Cohort A: mPFS was 4.0 m (95%CI: 3.6-8.7) in the ADT arm and 6.5 m (95%CI: 5.3-8.6) in the CT arm. Neither superiority nor inferiority of ADT over CT were demonstrated. ORR was 23% (ADT) vs 35% (CT). OS hazard ratio, ADT versus CT, was HR=1.91 (95% CI: 0.92-3.98), with one-sided p=0.9580. Adverse events (AE) were 96% vs 67% in the CT and ADT arm respectively; G3-5 AEs were 15% in both arms. HER 2 amplification was detected in 17% of cases evenly distributed in the 2 arms. Cohort B: ORR was 19% with 1 complete response. mPFS was 3.5 m (95%CI: 2.0-5.9) and median OS was 20.2 m (95%CI: 9.8-29.5). G3-5 AE were 4%.

Conclusions: PFS in R/M/U AR expressing SGCs ADT did not prove superior nor inferior. ADT sensitivity is seen independently of treatment sequence, line and HER2 amplification. ADT combined with CT and/or with HER2 inhibitors, depending on HER2 status, might represent a rational approach for future studies.

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Legal entity responsible for the study: EORTC.

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Venslovaite: Financial Interests, Personal, Full or part-time Employment, I am an employee of: EORTC. All other authors have declared no conflicts of interest.

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LBA37 Final results: Randomized assessment of cisplatin dosing interval for ototoxicity (RADIO) trial comparing chemoradiation (CRT) with cisplatin q3weekly to weekly for locally advanced squamous cell carcinoma of the head and neck (LASCCHN)

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Background: Most patients (pts) with HPV-related oropharyngeal cancer will be cured and live with longterm adverse effects of their treatment. We tested the hypothesis of less permanent hearing loss with cisplatin given weekly versus q3weekly with RT for LASCCHN in a randomized clinical trial.

Methods: Eligible adult LASCCHN pts were planned for curative intent CRT, considered suitable for q3weekly cisplatin and had adequate baseline hearing. RT included 70 Gy/35 fractions to areas of gross disease. Pts were randomized to concurrent cisplatin either 100 mg/m^2 days 1, 22 and 43 or 40 mg/m^2 weekly x 7 weeks. Co-primary endpoints were the incidence of ≥grade 2 audiometrically measured hearing impairment and hearing-related QoL, both measured at 1 year. All pts provided informed consent for this REB approved trial.

Results: 99 eligible pts (85 males/14 females) median age 61 years (range, 40-75 years) were enrolled at 3 academic cancer centers in Canada between Feb 2019 and June 2023. Baseline pt characteristics were well balanced. 94% of pts had p16-positive oropharyngeal cancer. 50 pts received cisplatin q3weekly for 3 (74%), 2 (22%) or 1 cycle (4%); and 49 pts received weekly cisplatin for a median of 6 cycles (range, 3-7); with similar mean cisplatin doses. Grade 3/4 acute toxicities occurred in 40% and 47% of pts, respectively. 47 pts were alive at 1-year in each arm and 1-year audiograms were available for 87 pts (93%). Hearing impairment ≥grade 2 at 1 year was present in 32 pts (64.0%) treated with q3weekly cisplatin and 20 pts (40.8%) treated with weekly cisplatin (p=0.027). The incidence of tinnitus (92.0% vs 73.5%, p=0.017) and need for hearing amplification (54.0% vs 36.7%, p=0.11) were higher with q3weekly cisplatin.

Conclusions: Grade 2/3 hearing impairment at 1 year was reduced by 40% with the use of weekly cisplatin given concurrent with RT compared to a q3weekly schedule. Rates of tinnitus and the need for hearing amplification were also reduced. Hearing-related QoL data were collected and will also be presented. Our results support the use of weekly cisplatin in pts with HPV-related LASCCHN to reduce longterm hearing morbidity.

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Legal entity responsible for the study: M. S. Kuruvilla.

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