851MO Final analysis of a phase II/III trial of post-operative chemoradiotherapy comparing 3-weekly cisplatin with weekly cisplatin in high-risk patients with squamous cell carcinoma of the head and neck (JCOG1008)

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Background: JCOG1008 was a multi-institutional randomized phase II/III trial which compared weekly cisplatin (CDDP)+RT (40 mg/m^2, qwk, 66 Gy/33Fr) with 3-weekly CDDP+RT (100 mg/m^2, q3wk, 66 Gy/33Fr) in post-operative high-risk squamous cell carcinoma of the head and neck (SCCHN). Interim analysis had demonstrated the non-inferiority of weekly CDDP+RT in overall survival (OS) with a better acute toxicity profile (J Clin Oncol. 2022;40(18):1980-1990). Here, we report the final analysis of JCOG1008.

Methods: The aim of the trial was to confirm the non-inferiority of weekly CDDP+RT (Arm B) to 3-weekly CDDP+RT (Arm A) in patients (pts) with post-operative high-risk SCCHN. Primary endpoint of phase III was OS, and secondary endpoints included relapse-free survival (RFS), local relapse-free survival (LRFS) and adverse events (AEs). A non-inferiority margin of hazard ratio (HR) was set at 1.32. The data used in this final analysis were obtained at 5 years after last patient enrollment.

Results: Between Oct 2012 and Dec 2018, 261 pts were enrolled (Arm A 132 pts, Arm B 129 pts). At final analysis with a median follow-up of 5.6 years, 5-year OS was 58.7% in Arm A and 71.2% in Arm B (HR 0.76, 95% CI, 0.52-1.12 [<1.32]), which maintained the non-inferiority of Arm B. 5-year RFS/LRFS was 53.0%/57.2% in Arm A and 64.3%/68.8% in Arm B (HR 0.81, [95% CI, 0.57-1.16]; HR 0.79, [95% CI, 0.54-1.14]), respectively. There were fewer deaths from any cause and cancer-specific deaths in Arm B (Arm A; 60/45 vs. Arm B; 48/32). Regarding disease events, local recurrence occurred in 21 pts in Arm A and 19 pts in Arm B; distant recurrence only occurred in 34 pts in Arm A and 24 pts in Arm B; and second primary disease occurred in 27 pts in Arm A and 31 pts in Arm B, the most common site of which was the esophagus. Regarding late AEs, any grade/grade 3 or more late AEs occurred in 91.5%/10.1% in Arm A and 94.2%/13.2% in Arm B.

Conclusions: At final analysis with 5-year follow up, the non-inferiority of weekly CDDP+RT was maintained. These results further support the use of weekly CDDP+RT as standard treatment.

Clinical trial identification: jRCTs031180135.

Legal entity responsible for the study: Head and Neck Cancer Study Group of the Japan Clinical Oncology Group (JCOG-HNCSG).

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852MO REWRITE—GORTEC 2018-02: Radiotherapy-durvalumab without prophylactic neck irradiation in squamous cell carcinoma of the head and neck

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Background: REWRITE, a multi-center single-arm phase II trial, was conducted to evaluate the neck control with durvalumab and RT restricted to the primary tumor site, with largely reduced-volume prophylactic neck irradiation (PNI) of N0 regions, in patients (pts) with SCCHN.

Methods: Pts with SCCHN T1-T4, N0-N2b non palpable, and only homolateral lymph node (LN) in radiological examinations, deemed ineligible for concomitant RT-CT were enrolled in this study. RT was delivered to the primary tumor and involved LN to a dose of 70Gy/33F over 6.5 weeks. Target volume included nodal level immediately adjacent to primary tumor/invaded LN to 52.8Gy, without any other PNI. Durvalumab was delivered during RT (1125 mg, Q3W) and was continued Q4W at 1500 mg for 6 months. The primary endpoint was regional nodal control rate in non-irradiated neck at 1 year, with an expected control rate of 92%.

Results: 57 pts (median age=74 years, male = 72%) were included. The main primary tumor site was larynx (n=22, 39%) and oropharynx (n=15, 26%). The main T staging was T2 (N=23, 40%) and T4 (N=20, 35%). N staging was N1-N2b for 18 pts (31%). PS was 1 for 31 pts (54%) and 2 for 16 pts (28%). Durvalumab was delivered for 3 cycles during RT for 46 pts (80%). 29 pts (50%) could receive 6 months adjuvant durvalumab as planned. 56/57 pts were eligible for the evaluation of primary endpoint. 2 patients (3.6% [IC95% = 0.44; 12.31%]) had a progression disease in non-irradiated N0 neck at 1 year, corresponding to a neck control rate of 96.4%. 23 pts had a relapse, with a majority occurring in primary tumor (n=14). 1-year OS rate was 70% [95% CI 56-80%]. RT was well tolerated, with 4 G3 toxicity occurred in 3 pts (mucositis, dysphagia and pneumonia aspiration). Two pts had a G5 durvalumab related toxicity (interstitial pneumonia and diabetes) and 1 patient had a G5 durvalumab and RT related toxicity (Mucositis).

Conclusions: The primary endpoint was met showing that very limited N0 neck irradiation was associated with a very low probability of nodal relapse in non-irradiated neck in this subset of frail pts with T1-T4 SCCHN. The regional control rate compared favorably to that observed in case of large PNI.

Clinical trial identification: EU Clinical Trials Register: 2018-001976-39.

Legal entity responsible for the study: GORTEC.

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853MO Setanaxib plus pembrolizumab for the treatment of recurrent or metastatic squamous cell carcinoma of the head & neck: Results of a randomized, double-blind phase II trial

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Background: Myofibroblastic cancer-associated fibroblasts (myCAFs) exclude CD8+ T cells from tumours and promote resistance to anti-PD-1 therapy (Ford K. *Cancer Res*. 2020;80:1846-60). NOX4 regulates myCAF differentiation; preclinical data show that the NOX1/4 inhibitor setanaxib (STX) overcomes myCAF-mediated immunotherapy resistance (Ford K. *Cancer Res*. 2020;80:1846-60). Pembrolizumab (PMB) is used as

first-line monotherapy for patients (pts) with recurrent or metastatic head & neck squamous cell carcinoma (rmHNSCC), where ~85% of tumours have moderate/high myCAF levels (≥5%) and response rates are low (Harrington KJ. *J Clin Oncol.* 2023;41:790-802; Marsh D. *J Pathol.* 2011;223:470-81).

Methods: This randomized, double-blind phase II trial (NCT05323656) evaluated the effect of STX added to PMB in adult pts with rmHNSCC, a combined positive score ≥1, and tumour CAF levels ≥5%. Randomization was 1:1 (stratified by HPV status) to oral STX 800 mg BID or placebo, on top of PMB 200 mg IV every 3 weeks, for ≤24 months. Primary endpoint was best % change from baseline in tumour size (RECIST v1.1); secondary endpoints included PFS, OS, and change from baseline in biomarkers, incl. intratumoural CD8+ T cells.

Results: N=55 pts were randomized. No difference in the primary endpoint was seen but PFS and OS were both statistically significantly greater in the STX arm, with nominal p values below the 0.2 significance threshold level set for this study (Table). No difference in the overall incidence of Grade ≥3 adverse events was seen; mild/moderate hypothyroidism was more common with STX (8 vs 3 pts). Paired biopsy transcriptomic analyses showed statistically significantly more CD8+ T cells in tumour tissue from STX pts.

Table: 853MO

Endpoint	Setanaxib (STX) + pembrolizumab (PMB), n=27	Placebo + pembrolizumab (PMB), n=28
Best % change from baseline in tumour lesion size		
Adjusted LS mean (SE)	-7.88 (9.323)	-12.93 (8.997)
LS mean difference (80% CI)	5.05 (-11.9, 22.0)	
Progression-free survival (PFS)		
Number of events (%)	17 (63%)	21 (75%)
Median PFS, months	5.0	2.9
Progression-free at 6 months	41%	25%
Hazard ratio (80% CI)	0.58 (0.38, 0.89; nominal p value=0.1)	
Overall survival (OS)		
Number of events (%)	6 (22%)	13 (46%)
OS at 9 months	88%	58%
Hazard ratio (80% CI)	0.45 (0.24, 0.85; nominal p value=0.1)	

Conclusions: STX added to PMB showed statistically significant effects on PFS and OS in pts with rmHNSCC. STX was well tolerated. This combination could have utility in targeting myCAF-rich, 'immune-excluded' tumours.;

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854MO Avelumab-cetuximab-radiotherapy (RT) versus standards of care in patients with locally advanced squamous cell carcinoma of head and neck (LA-SCCHN): Final analysis of randomized phase III GORTEC 2017-01 REACH trial

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Background: Based on a potential synergistic effect of anti—PD-L1 avelumab plus cetuximab and RT, this combination was tested in a randomized trial against two standards of care (SOC) in LA-SCCHN.

Methods: The trial comprised 2 cohorts of patients (pts): fit for cisplatin (100 mg/m^2, Q3W) and unfit for cisplatin. The SOC was IMRT 70 Gy / 6.5 weeks with cisplatin in fit Cohort and with cetuximab in unfit Cohort (*Bonner, 2006*). In both cohorts, experimental arm (Exp) was IMRT 70 Gy plus weekly cetuximab and avelumab 10 mg/kg at Day-7 and every 2 weeks during RT followed by avelumab every 2 weeks for 1 year. The primary endpoint was progression-free survival (PFS). In unfit Cohort, 115 events were needed / 277 pts to detect a HR of 0.62 (1-sided α error 0.05; power 80%). In fit Cohort, 166 events were needed / 430 pts to detect a HR of 0.64 (2-sided α error 0.05; power 80%).

Results: Between 2017 and 2020, 707 patients were randomized, 6 withdrew consent. Unfit Cohort: 275 pts, median age 67 years, 61% OPC including 35% p16+. The number of events was reached in 2021, the current analysis is a long-term update. With a median follow-up of 47.7 months (IQR 39.4-56.0) and 200 PFS events, HR was 0.80 (95%CI 0.60-1.06); 4-year PFS rate was 33.7% (95%CI 26.2%-42.2%) in Exp vs 18.4% (95%CI 12.5%-26.1%) in SOC-cetux. Distant metastasis rate remained lower in Exp (subHR 0.24 (95%CI 0.11-0.49)). No significant difference in OS was seen between arms (HR 1.05 (95%CI 0.76-1.44). Fit Cohort: 426 pts, median age 59 years, 70% oropharyngeal cancer (OPC) including 49% p16+. With a median follow-up of 50.8 months (IQR 45.8-57.4) and 224 PFS events, PFS was significantly lower in Exp than in SOC-cisplatin: HR 1.40 (95%CI 1.12-1.75), p=0.012; 4-year PFS rate 42.3% (95%CI 35.7%-49.2%) in Exp *vs* 54.7% in SOC-cisplatin (95%CI 47.8%-61.4%). OS was also lower in Exp than in SOC-cisplatin (HR=1.45, 95%CI 1.12-1.87, p=0.017).

Conclusions: In cisplatin-unfit pts, a favorable effect of adding avelumab to cetuximab-RT was seen on PFS and distant metastases but not on OS. In cisplatin-fit pts, the SOC cisplatin-RT was superior to combination of cetuximab-avelumab-RT.

Clinical trial identification: NCT02999087.

Legal entity responsible for the study: GORTEC.

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