Choice of Poster Presentations

Poster Discussion Session

Lisa F. Licitra, Robert I. Haddad, Caroline Even, Makoto Tahara, et al.

EAGLE: A phase 3, randomized, open-label study of durvalumab (D) with or without tremelimumab (T) in patients (pts) with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC).

Conclusions: D and D+T did not demonstrate a statistically significant improvement in OS compared to standard chemotherapy in pts with R/M HNSCC. Median OS and ORR of D arm were similar to other studies with checkpoint inhibitors. The SOC arm outperformed what has been seen for SOC arms in previous studies; subsequent immunotherapy may have confounded the OS analyses. The safety profile for D and D + T in R/M HNSCC is consistent with previous trials. Clinical trial information: NCT02369874

<table>
<thead>
<tr>
<th></th>
<th>D (n = 240)</th>
<th>D+T (n = 247)</th>
<th>SOC (n = 249)</th>
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<tbody>
<tr>
<td>Median OS, mo (95% CI)</td>
<td>7.6 (6.1–9.8)</td>
<td>6.5 (5.5–8.2)</td>
<td>8.3 (7.3–9.2)</td>
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<td>Survival rate, % (95% CI)</td>
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<tr>
<td>12 mo</td>
<td>37.0 (30.9–43.1)</td>
<td>30.4 (24.7–36.3)</td>
<td>30.5 (24.7–36.4)</td>
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<tr>
<td>24 mo</td>
<td>18.4 (13.3–24.1)</td>
<td>13.3 (8.9–18.6)</td>
<td>10.3 (5.7–16.5)</td>
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<tr>
<td>ORR, % (95% CI)</td>
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<tr>
<td>12.9</td>
<td>17.9 (13.3–23.3)</td>
<td>18.2 (13.6–23.6)</td>
<td>17.3 (12.8–22.6)</td>
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<td>DOR, mo</td>
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Palbociclib plus cetuximab versus placebo plus cetuximab in platinum-resistant, cetuximab-naive, HPV-unrelated head and neck cancer: A double-blind randomized phase II trial (PALATINUS).

Conclusions: Among pts with platinum-resistant, HPV-unrelated HNSCC, PAL plus cetuximab resulted
in a trend of prolongation of median OS compared with cetuximab. Clinical trial information: NCT02499120

David M. Cognetti, Jennifer Maria Johnson, Joseph M. Curry, Frank Mott, et al.

Results of a phase 2a, multicenter, open-label, study of RM-1929 photoimmunotherapy (PIT) in patients with locoregional, recurrent head and neck squamous cell carcinoma (rHNSCC).

Conclusions: These data indicate that RM-1929 PIT treatment was generally well tolerated with majority of AEs as mild to moderate in severity. Preliminary data showed favorable response rates in a heavily pre-treated population. A global phase 3 clinical trial is currently underway. Clinical trial information: NCT02422979


Primary analysis of Phase 2 results of cemiplimab, a human monoclonal anti-PD-1, in patients (pts) with locally advanced cutaneous squamous cell carcinoma (laCSCC).

Conclusions: Cemiplimab 3 mg/kg Q2W showed substantial antitumor activity, durable responses, and acceptable safety profile in pts with laCSCC. These data strongly support the recent FDA approval of cemiplimab-rwlc for pts with mCSCC or laCSCC who are not candidates for curative surgery or curative radiation. Clinical trial information: NCT02760498

Adam Luginbuhl, Jennifer Maria Johnson, Madalina Tuluc, Stacey Mardekin, et al.

Discordant treatment response in primary tumors and lymph node metastases after four weeks of preoperative PD-1 blockade in head and neck squamous cell carcinoma (HNSCC).

Conclusions: Early histologic evaluation of TE in patients with HNSCC receiving immunotherapy demonstrate a wide variety of response between the primary tumor and LNs. Further investigations will lend insight into complex interactions of cancer cells with the microenvironment. Clinical trial information: NCT03238365

Fenghua Wang, Xiao-Li Wei, Ji Feng Feng, Qi Li, Nong Xu, et al.
Recombinant humanized anti-PD-1 monoclonal antibody (JS001) in patients with refractory/metastatic nasopharyngeal carcinoma: Interim results of an open-label phase II clinical study.

Conclusions: Toripalimab has demonstrated a manageable safety profile and encouraging clinical activity in the largest check-point blockade study in NPC to date. A change in plasma EBV DNA copy number might serve as a predictive marker for favorable clinical response. Patients will be continuously monitored for additional safety and survival readouts. Clinical trial information: NCT02915432


Activity and tolerability of BLU-667, a highly potent and selective RET inhibitor, in patients with advanced RET-altered thyroid cancers.

Conclusions: BLU-667 demonstrates potent, durable and broad antitumor activity and is well tolerated in MTC/PTC pts regardless of MKI resistance and may significantly improve outcomes for pts with RET-altered thyroid cancers. Enrollment of the expansion is ongoing with registrational intent. Clinical trial information: NCT03037385

Dapeng Li, Ping Zhang Tang, Xiaohong Chen, Minghua Ge, et al.

Anlotinib treatment in locally advanced or metastatic medullary thyroid carcinoma: A multicenter, randomized, double-blind, placebo-controlled phase IIB trial.

Conclusion: ALTER01031 met its primary endpoint of PFS shows that anlotinib treatment is effective and well tolerated. The safety profile was consistent and no new adverse events were identified. These data potentially extend the role of anlotinib monotherapy as a new therapy strategy for MTC patients. Clinical trial information: NCT02586350

Alan Loh Ho, Nathan R. Foster, Alexander J. Zoroufy, Francis P. Worden, et al.

Alliance A091404: A phase II study of enzalutamide (NSC# 766085) for patients with androgen receptor-positive salivary cancers.

Conclusions: This is the first prospective trial evaluating an antiandrogen alone for AR+ SGCs. The failure to meet the protocol-defined measure of success was due in part to the lack of durability of initial responses. The clinical activity observed suggests the AR-dependence of AR+ SGCs, even among those
previously treated with other hormonal therapies. Support: U10CA180821, U10CA180882; Astellas; https://acknowledgments.alliancefound.org. Clinical trial information: NCT02749903

Jia-Wei Lv, Ying Sun, Yu-Pei Chen, Guan-Qun Zhou, et al.

**Longitudinal circulating Epstein–Barr virus DNA response to induction chemotherapy and chemoradiotherapy to identify biological phenotypes in EBV-associated nasopharynx of head and neck cancer.**

**Conclusions:** We propose investigate risk-adapted chemotherapy de-intensification and intensification strategies based on the four novel phenotypes, which could shape the individualized treatment of LA-NPC. Our study highlights the feasibility of liquid biopsy for real-time therapeutic adaptation.


**Mature results of the LCCC1413 phase II trial of de-intensified chemoradiotherapy for HPV-associated oropharyngeal squamous cell carcinoma.**

**Conclusions:** Clinical outcomes with a highly de-intensified CRT regimen of 60 Gy IMRT with concurrent low-dose cisplatin are excellent in patients with HPV-associated OPSCC. Clinical trial information: NCT02281955

Julie E. Bauman, Jonathan Harris, Ravindra Uppaluri, Min Yao, et al.

NRG-HN003: Phase I and expansion cohort study of adjuvant cisplatin, intensity-modulated radiation therapy (IMRT), and MK-3475 (Pembrolizumab) in high-risk head and neck squamous cell carcinoma (HNSCC).

**Conclusions:** The RP2S is pembrolizumab 200 mg IV q 3 weeks for 8 doses, starting the week before adjuvant CRT. This regimen was safe and feasible in a cooperative group setting. irAE were rare in this population. Clinical trial information: NCT02775812
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<th>Week of Adjuvant IMRT</th>
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<td>LoadinCRT</td>
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<tr>
<td>IMRT</td>
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<td>(60 Gy, 2 Gy/Fx /day) – all schedules</td>
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<tr>
<td>Cisplatin</td>
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<td>Pemembrinolizum</td>
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- 2/week IV – all schedules
- Pemembrinolizum ab 200 mg IV

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<th>Schedule</th>
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<tr>
<td>3 (Starting)</td>
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<td>2 (1st De-escalation)</td>
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<td>1 (2nd De-escalation)</td>
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Poster Session

Julie E. Bauman, Nabil F. Saba, Trisha Michel Wise-Draper, Douglas Adkins, et al.

**CDX3379-04: Phase II evaluation of CDX-3379 in combination with cetuximab in patients with advanced head and neck squamous cell carcinoma (HNSCC).**

**Conclusions:** CDX-3379 in combination with cetuximab is well tolerated with the primary toxicity of diarrhea. Signs of antitumor activity were observed in these cetuximab-resistant HNSCC pts, including an ongoing, durable CR. Complete stage 1 results will be presented. Clinical trial information: NCT03254927

Felix Keil, Maximilian Hartl, Gabriela Altorjai, Martin Pecherstorfer, et al.

**Induction chemotherapy with docetaxel, cisplatin and cetuximab versus docetaxel, cisplatin and 5-fluorouracil followed by radiotherapy with cetuximab for locally advanced or inoperable squamous cell carcinoma of the head and neck: Promising results of a randomized phase II AGMT-trial.**

**Conclusions:** In conclusion, TPC is a feasible and tolerable therapy regimen and can be applied within one day with less hematological toxicities. In contrast, more local reactions were observed after TPC. TPC containing ICT leads to improved response rates, while OS and PFS were similar in both arms. TRM was extremely low with 1%. Therefore, we conclude, that TPC containing ICT could be a considerable therapeutical alternative for patients with locally advanced or unresectable stage III or IV SCCHN, who are eligible for ICT. Clinical trial information: 2011-005540-99.

Martin David Forster, Joseph J. Sacco, Anthony Hee Kong, Graham Wheeler, et al.

**EACH: A randomised phase II study evaluating the safety and anti-tumour activity of the combination of avelumab and cetuximab relative to avelumab monotherapy in recurrent/metastatic head and neck squamous cell cancer.**
Methods: EACH is a randomised phase II trial preceded by a safety run-in phase. Eligible patients have histologically or cytologically confirmed measurable recurrent or metastatic squamous cell carcinoma of any site in the safety run-in phase, and HNSCC in phase II, that is considered incurable by local therapies. The safety run-in has a single arm de-escalating design, aiming to establish the safety of cetuximab with avelumab and determine the optimal dose of cetuximab within this combination. The safety run-in has a dosing schedule of avelumab (10 mg/kg) + cetuximab (500 mg/m²) intravenously every 2 weeks, with de-escalation of cetuximab to 400 mg/m² and 300 mg/m² if necessary. The safety run-in phase commenced recruitment in July 2018 and is ongoing. The phase II component will randomize 114 HNSCC patients between either avelumab + cetuximab at the dose determined by the safety run-in phase or avelumab (10 mg/kg) alone. Treatment will be in 4-week cycles for up to one year. The primary endpoint in the safety run-in phase is the occurrence of dose limiting toxicities, and in phase II is Disease Control Rate at 24 weeks, using iRECIST. Blood and fresh tissue will be collected for exploratory translational studies, which will focus on the identification of potential novel predictive biomarkers for response. Clinical trial information: NCT03494322

Cécile Mertens, Hervé Le Caer, Cécile Ortholan, Emmanuel Blot, et al.

ELAN-ONCOVAL (Elderly Head and Neck Cancer-Oncology Evaluation) study: Evaluation of the G8 screening tool and the ELAN geriatric evaluation (EGE) for elderly patients (pts) with head and neck squamous cell carcinomas (HNSCC).

Conclusions: The G8 screening tool is not appropriate for HNSCC pts. The EGE was feasible and had better sensitivity and specificity. Oncologists and geriatricians must continue such collaboration to propose tailored treatments. Clinical trial information: NCT03614936