News Briefing: Highlights from the 2018 Multidisciplinary Head and Neck Cancers Symposium

Tuesday, February 13, 2018
News Briefing: Highlights from the 2018 Multidisciplinary Head and Neck Cancers Symposium

Moderator: Danielle Margalit, MD, Dana-Farber Cancer Institute

A Randomized, Open-Label, Multicenter, Global Phase 2 Study of Durvalumab (D), Tremelimumab (T), or D Plus T in Patients With PD-L1 Low/Negative Recurrent or Metastatic (R/M) Head and Neck Squamous Cell Carcinoma (HNSCC): CONDOR

Lillian Siu, MD, Princess Margaret Cancer Centre

Safety evaluation of nivolumab (Nivo) concomitant with platinum-based chemoradiotherapy (CRT) for intermediate (IR) and high-risk (HR) local-regionally advanced head and neck squamous cell carcinoma (HNSCC): RTOG Foundation 3504

Maura Gillison, MD, PhD, University of Texas MD Anderson Cancer Center

A Phase II Trial of Cabozantinib for the Treatment of Radioiodine (RAI)-refractory Differentiated Thyroid Carcinoma (DTC) in the First-line Setting

Marcia S. Brose, MD, PhD, Perelman School of Medicine, University of Pennsylvania

OPTIMA—A Phase II Trial of Induction Chemotherapy Response-Stratified RT Dose and Volume De-escalation for HPV+ Oropharynx Cancer: Efficacy, Toxicity, and HPV Subtype Analysis

Tanguy Seiwert, MD, University of Chicago Medicine
Safety evaluation of nivolumab (Nivo) concomitant with platinum-based chemoradiotherapy (CRT) for intermediate (IR) and high-risk (HR) local-regionally advanced head and neck squamous cell carcinoma (HNSCC): RTOG Foundation 3504


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Disclosure

• Please list your employer along with any potential conflicts of interest.

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• If you have none, please enter the following statement: “I have no conflicts of interest to disclose.”
Background

- Patients diagnosed with mouth and throat cancer ("head and neck cancer") often present with advanced disease and relapse within two years.
- An antibody to the PD-1 checkpoint receptor (nivolumab) improves survival of patients whose cancer has progressed after platinum chemotherapy.
- Incorporating these drugs into initial therapy of head and neck cancer has the potential to improve survival.
- This study was designed to evaluate the safety of nivolumab when added to four standard of care chemotherapy and radiation platforms.
- Here we present data on the two platforms that include cisplatin.
RTOG Foundation 3504

**High-Risk SCC**
OC, Larynx, Hypopharynx, p16 negative OP
AJCC 7
T1-2N2a-N3
T3-4N0-3

**Intermediate-risk**
p16-positive OP
>10 pack-years
T1-2N2b, T3-4N0-3
≤10 pack-years
T4N0-N3, T1-3N3

**Arm 1:**
Nivolumab 240 mgs Q14D X 10
Cisplatin 40 mg/m²/wk X 7
70 Gy/35 Fx/7 weeks

**Arm 2:**
Nivolumab 240 mgs Q14D X 1 then 360 mgs Q21D X 6
Cisplatin 100 mg/m² Q21D X 3
70 Gy/35 Fx/7 weeks

**Adjuvant:**
Nivolumab 480 mgs Q28D X 7
## Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Arm 1 Cisplatin 40 mg/m2/wk n=10</th>
<th>Arm 2 Cisplatin 100 mg/m2 Q21D n=10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median, min-max</td>
<td>56, 48-66</td>
<td>58, 35-76</td>
</tr>
<tr>
<td>Male Gender, n</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Caucasian Race, n</td>
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<td>8</td>
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<tr>
<td>Zubrod PS 1, n</td>
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<td>7</td>
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<tr>
<td>Risk category</td>
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<tr>
<td>Intermediate, n</td>
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<td>8</td>
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<tr>
<td>High, n</td>
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<td>2</td>
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<tr>
<td>Positive HPV status, n</td>
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<td>8</td>
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<tr>
<td>T3-4 stage, n</td>
<td>8</td>
<td>8</td>
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<tr>
<td>N2c-3 stage, n</td>
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<td>5</td>
</tr>
<tr>
<td>Smoking &gt; 10 PY, n</td>
<td>8</td>
<td>3</td>
</tr>
</tbody>
</table>
Treatment Summary

• The addition of nivolumab to standard therapy raised no safety concerns.
• All evaluable patients completed radiation therapy.
• 15 of 17 patients received a cisplatin dose at or above the effective dose.
• 3 of 18 patients had treatment discontinued due to known side effects of nivolumab (blurred vision, diarrhea and joint pain).
• 6 of 8 patients completed a year of nivolumab therapy.
Conclusions

• The addition of nivolumab to standard of care cisplatin and radiation therapy was feasible and no new safety concerns were identified.

• Standard of care therapy was not compromised.

• A total of one year of nivolumab therapy was feasible and tolerable.

• Safety evaluation of nivolumab addition to other platforms is ongoing.

• Phase 3 evaluations of the clinical benefit are ongoing.
Interview Requests and Other Questions

press@astro.org

703-286-1600

On-site Press Office in Scottsdale
   Parke Room, Westin Kierland
   February 15-16, 8am-4pm MT

A video of the recording will be available following the briefing at
www.astro.org/AMpress