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Preoperative durvalumab (D) with or without tremelimumab (T) for resectable head and neck squamous cell carcinoma (HNSCC)

M.H. Hong[1], C.G. Kim[1], D.H. Kim[2], S.M. Lim[1], B-C. Ahn[1], S-H. Kim[2], Y.M. Park[2], H. Park[3], G. Park[4], I. Jung[4], B.C. Cho[1], Y.W. Koh[2], H.R. Kim[1]

[1] Division of Medical Oncology, Department of Internal Medicine, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea, [2] Department of Otorhinolaryngology, Yonsei University College of Medicine, Seoul, Republic of Korea, [3] Department of Pathology, Yonsei University College of Medicine, Seoul, Republic of Korea[4] Division of Biostatics, Department of Biomedical Systems Informatics, Yonsei University College of Medicine, Seoul, Republic of Korea

Background

Although antibodies that block PD-1/PD-L1 axis improve survival in patients with recurrent and/or metastatic HNSCC, safety and efficacy of neoadjuvant immunotherapy with PD-L1 with or without CTLA-4 blockade has not been explored. Here, we evaluate the safety and efficacy of a single dose of preoperative D with or without T (D+/-T) in patients with resectable HNSCC.

Methods

Patients with locally advanced but resectable HNSCC were eligible. Enrolled patients were randomized into D or D+T, stratified by primary site and human papilloma (HPV) infection status. A single dose of preoperative D (1500mg) or D+T (1500mg+75mg) was administered, with surgery planned 2 to 8 weeks later for curative resection. Postoperative (chemo) radiation was prescribed based on standard guidelines, followed by maintenance with D every 4 weeks for 1 year. The primary objective was to determine the local recurrence rate. Secondary endpoints included pathologic response, safety, tolerability, survival outcome, and exploration of immune dynamics.

Results

As of May 14, 2021 for interim analysis, a total of 44 patients were enrolled and received surgical resection with available data for pathologic response (D: 20 patients, D+T: 24 patients). Oropharyngeal cancer was most common (n=22), followed by hypopharyngeal (n=9), oral cavity (n=8), and laryngeal cancer (n=5). Human papilloma virus-mediated cancer was observed in 20 patients (45.4%). Neaoadjuvant D+/-T had an acceptable safety profiles and was not associated with delays in surgery or unexpected adverse events. Tumor shrinkage was observed in 31 patients (70.5%), with 16.0% of average tumor shrinkage (95% CI; 4.7% to 27.3%) in the overall population. Major pathologic response (no more than 10% of viable tumor cells) was achieved in 3 patients (6.8%), including 2 cases with pathologic complete response (4.5%). During median follow-up duration of 176 days after surgery, local recurrence was documented in 2 patients (4.5%).

Conclusions

These early data suggested that preoperative D+/-T was safe and feasible and had the potential to provide clinical benefits for patients with resectable HNSCC. The trial is ongoing and the updated outcomes with immune correlates will be presented with ESMO.

Clinical trial identification

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Legal entity responsible for the study

The authors.

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Disclosure

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