TPS6119 **Poster Session**

TRENT-002: A prospective, multicenter, randomized controlled phase II study to evaluate the efficacy and safety of salvage preoperative PD-1 inhibitor combined with chemotherapy neoadjuvant therapy in recurrent laryngeal/hypopharyngeal squamous cell carcinoma (L/HPSCC).

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Background: Salvage surgery is considered the standard of care for patients with resectable recurrent L/HPSCC. However, salvage surgery achieves durable disease control in only 20% to 50% of patients. The PATHWay study showed that the subgroup that received salvage therapy indicated that adjuvant pembrolizumab could significantly improve PFS compared with placebo, but there is no OS data. This muti-center, prospective, randomized controlled phase II study will evaluate efficacy and safety of PD-1 inhibitors plus chemotherapy as neoadjuvant therapy in recurrent L/HPSCC. **Methods:** Patients who meet the inclusion criteria will be divided into groups according to whether they had received radiotherapy in the past. Arm 1 and Arm 2 are the groups that had not received radiotherapy in the past (N=100), and Arm 3 and Arm 4 are the groups that had received radiotherapy (N=160). Arm 1 and Arm 2 will be randomly assigned at a 1:1 ratio. Arm 1 will receive 3 cycles of pembrolizumab + nab-paclitaxel + cisplatin, followed by surgery. After surgery, patients will be stratified according to the presence or absence of high-risk factors (extranodal extension or positive margins). The high-risk group will receive concurrent chemoradiotherapy + pembrolizumab maintenance therapy (up to 15 cycles), and the low-risk group will receive radiotherapy + pembrolizumab maintenance therapy (up to 15 cycles). Arm 2 will undergo surgery directly, followed by concurrent chemoradiotherapy/ radiotherapy. The total radiation dose is 60-66 Gy, 2.0 Gy/fraction for high-risk group and 44-50 Gy, 2.0 Gy/fraction for low-risk group. Similarly, Arm3 and Arm4 will be randomly assigned in a 1:1 ratio. Arm 3 will receive 3 cycles of pembrolizumab + nab-paclitaxel + cisplatin, followed by surgery, and pembrolizumab maintenance treatment after surgery. Arm 4 will be directly given surgery, and after surgery, the doctor will choose observation / re-radiotherapy or chemoradiotherapy. Eligibility criteria will include patients with squamous cell carcinoma of the larynx and hypopharynx confirmed by histology and/or cytology; patients with recurrence of primary tumor or second primary tumor after receiving curative treatment; At least 6 months after the last platinum-containing treatment; ECOG performance status 0-1. Primary end points is 2y-PFS. Secondary end points include ORR, pCR, 3y-OS, safety. Recruitment is ongoing and will continue until 260 patients are enrolled. Clinical trial information: NCT06793761. Research Sponsor: None.