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Tam-Peli versus chemotherapy in heavily pretreated recurrent/metastatic nasopharyngeal carcinoma (R/M NPC): A multicenter, randomized, open-label, phase 3 study (TAISHAN-301)

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Background

R/M NPC remains difficult to treat after immunotherapy and multiple lines of chemotherapy. Tambotatug pelitecan (Tam-Peli, YL201) is a novel B7-H3-directed antibody-drug conjugate (ADC). TAISHAN-301 is the first phase 3 study evaluating the efficacy and safety of a B7-H3-directed ADC vs treatment of physician's choice (TPC) in heavily pretreated R/M NPC.

Methods

Eligible patients (pts) with R/M NPC previously treated with PD-(L)1 inhibitor and ≥ 2 lines of chemotherapy, including ≥ 1 line of platinum-based regimen, were randomized 1:1 to receive Tam-Peli (2.4 mg/kg IV Q3W; maximum 200 mg) or TPC (docetaxel, gemcitabine, or capecitabine). Randomization was stratified by ECOG PS (0 or 1) and liver metastasis (yes or no). Co-primary endpoints were ORR as assessed by blinded independent central review (BICR) and OS. The key secondary endpoint was PFS by BICR. The prespecified interim analysis was conducted to test ORR for superiority.

Results

As of 17 Mar 2026, 431 pts were randomized to receive Tam-Peli (n=215) or TPC (n=216) with balanced baseline characteristics. At a median follow-up of 5.2 months, more pts were on treatment in Tam-Peli arm than in TPC arm (61.9% vs 35.6%). Tam-Peli significantly improved confirmed ORR by BICR vs TPC (50.8% vs 25.8%; odds ratio [OR] 2.9, 95% CI 1.7-5.0; $p < 0.0001$). ORR benefit was consistent across subgroups, including pts with liver metastasis (OR 4.3, 95% CI 2.0-9.2) and those who progressed after > 2 prior lines of treatment (OR 5.7, 95% CI 2.5-12.7). DCR was 93.7% vs 75.8%, and median DoR was 7.9 vs 6.4 months. Although OS and PFS data were immature at cutoff, a favourable PFS trend was observed. Grade ≥ 3 treatment-related adverse events occurred in 49.3% vs 51.7% of patients, with neutropenia being the most common (27.0% vs 29.7%). No interstitial lung disease was observed. One treatment-related death was reported in each arm.

Conclusions

TAISHAN-301 met its primary endpoint of ORR at this prespecified interim analysis. Tam-Peli demonstrated statistically significant and clinically meaningful ORR improvement over TPC with a manageable safety profile, establishing Tam-Peli as a potential new standard of care for later-line R/M NPC.

Clinical trial identification

NCT06629597.

Legal entity responsible for the study

MediLink Therapeutics (Suzhou) Co., Ltd.

Funding

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Disclosure

X. Zhang: Financial Interests, Personal, Full or part-time Employment: MediLink Therapeutics (Suzhou) Co., Ltd. S. Chin: Financial Interests, Personal, Full or part-time Employment: MediLink Therapeutics (Suzhou) Co., Ltd. J. Cai: Financial Interests, Personal, Full or part-time Employment: MediLink Therapeutics (Suzhou) Co., Ltd. T. Xue: Financial Interests, Personal, Full or part-time Employment: MediLink Therapeutics (Suzhou) Co., Ltd. All other authors have declared no conflicts of interest.

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