# (PS2131) ANTI-PD-1-ANTIBODY (TISLELIZUMAB) PLUS CHIDAMIDE, LENALIDOMIDE AND ETOPOSIDE FOR REFRACTORY/RELAPSED EXTRANODAL NK/T-CELL LYMPHOMA, NASAL TYPE : A PROSPECTIVE, MULTICENTER, SINGLE-ARM TRIAL

**Topic:** 20. Other aggressive lymphomas

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## Background

Extranodal Natural Killer/T-Cell Lymphoma (ENKTL) is a highly aggressive subtype of non-Hodgkin lymphoma with a markedly higher incidence in Asia. Patients with Refractory/Relapsed-ENKTL(r/r-ENKTL) face a dismal prognosis and have limited therapeutic options.

## Aims

To evaluate the efficacy and safety of a novel regimen comprising Tislelizumab, Chidamide, Lenalidomide and Etoposide in patients with r/r-ENKTL.

## Methods

This was a prospective, single-arm, open-label, multicenter clinical trial enrolling adult patients with r/r-ENKTL who had received at least one prior systemic therapy. Patients received 6 cycles of combination therapy comprising Tislelizumab (200mg, Day 1), Chidamide (20mg, biw), Lenalidomide (25mg, Days 1-10) and Etoposide (100mg/m$^2$, Days 1-3) every 21 days, followed by 10 cycles of Tislelizumab maintenance (200mg, Day1) every 21 days. The primary endpoints were objective response rate (ORR) and progression-free survival (PFS). This trial is registered at ClinicalTrials.gov (NCT04038411).

## Results

From June 2020 to December 2025, 38 eligible patients with r/r-ENKTL were enrolled from 5 centers. The final follow-up occurred on February 20, 2026, with a median follow-up of 32 months (range: 2-67 months). The median age of the cohort was 39 years (range, 17-63 years). All patients received at least four cycles of induction chemotherapy. Among the 38 efficacy-evaluable patients, the overall response rate (ORR) was 84.2% (32/38), including a complete response (CR) rate of 60.5% (23/38). During Tislelizumab maintenance therapy, an additional one patients achieved CR, resulting in a cumulative CR rate of 65.8% (25/38) at the end of maintenance treatment. The median progression-free survival (PFS) was 49.0 months (95%CI: 24.3-3.7). Estimated PFS rates at 1, 2, and 5 years were 72.7%, 55.5%, and 42.3%, respectively. Median overall survival (OS) was not reached; corresponding 1-year, 2-year, and 5-year OS rates were 81.1%, 69.9%, and 54.9%. At last follow-up, 17 patients remained in continuous CR. The most common treatment-related adverse events (TRAEs) were anemia (83.3%), leukopenia (80.0%), neutropenia (80.8%), and thrombocytopenia (56.7%). The most frequent grade ≥3 TRAE was neutropenia (46.7%). Immune-related adverse events of grade 3 or higher included one case each of hypothyroidism and hyperglycemia.

| Characteristic | Total (%) |
|---|---|
| Sex (male) | 27(71.1) |
| B symptoms (Yes) | 14(36.8) |
| CA Stage(Ⅲ-Ⅳ) | 36(94.7) |
| PINK score<br>0-2<br>3-4 | <br>27(71.1)<br>11(28.9) |
| Prior PD-1 mAb use | 3(7.9) |

## Summary/Conclusion

This regimen demonstrated promising efficacy and a favorable safety profile in patients with r/r-ENKTL.