Envafolimab Plus Chemoradiotherapy for Locally Advanced NPC, a Prospective, Single Armed Phase II Trial.

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BACKGROUND

- The effect of Gemcitabine plus cisplatin (GP) chemotherapy for locoregionally advanced nasopharyngeal carcinoma (LANPC) is still unsatisfied.
- The addition of Immune checkpoint inhibitors to GP could significantly improve the survival in recurrent or metastatic NPC.
- In this study, we aim to evaluate the efficacy and safety of Envafolimab (PD-L1) with curative chemoradiotherapy for the patients with LANPC (Clinical trial information: NCT05397769).

RESULTS

- From June 14th 2022 to December 13th, 2022, a total of 37 patients were enrolled at Sun Yat-sen University Cancer Center.
- As of May 4th, 2023, 36 patients had completed induction chemotherapy treatment. the median follow-up is 7.38 months.

Table 1. Baseline demographics and disease

Characteristic	Patients (n=36)
Age (median-yr)	44
Male	23 (63.9%)
T stage, n (%)	
T1	1 (2.8%)
T2	5 (13.9%)
T3	21 (58.3%)
T4	9 (25.0%)
N stage, n (%)	
N1	6 (16.7%)
N2	16 (44.4%)
N3	14 (38.9%)
M stage, n (%)	
M0	36 (100.0%)
TNM stage, n (%)	
Ⅲ	17 (47.2%)
ⅣA	19 (52.8%)

METHODS

Study design: prospective, single-arm, phase 2

Key eligibility criteria
- Age 18-65
- Staged TxN2-3M0 or T4N1M0(AJCC 8th) non-keratinizing untreated LANPC

→ **Induction chemotherapy**
Gemcitabine (1g/m2, d1/8, Q3W)
+ Cisplatin (80 mg/m2, d1, Q3W)
+ Envafolimab (300mg, d1, Q3W)
3 cycles

→ **Concurrent chemotherapy**
CCRT(GTVnx 68-70Gy/30-33f, 5d/w,6-7w)
+ DDP (100 mg/m2, d1, Q3W)
+ Envafolimab (300mg, d1, Q3W)
2 cycles

→ **Maintenance treatment**
Envafolimab (300mg, d1, Q3W)
for a year

Enpoint

- Primary endpoint: 3-year progress-free survival
- Secondary endpoints: objective response rate(ORR), the disease control rate(DCR), locoregional failure-free survival, distant metastasis-free survival, and toxicity.

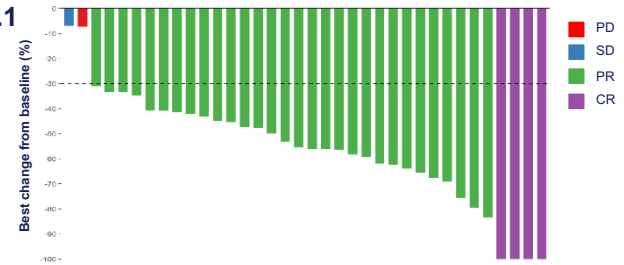
Efficacy:

- The ORR and DCR rate were 94.4%(95%CI: 81.3%, 99.3%) and 97.2%(95%CI: 85.5%, 99.9%).

Table 2. Best response based on RECIST 1.1 (n=36)

	n (%)	95%CI
ORR	34 (94.4%)	81.3%, 99.3%
DCR	35 (97.2%)	85.5%, 99.9%
CR	4 (11.1%)	
PR	30 (83.3%)	
SD	1 (2.8%)	
PD	1 (2.8%)	

Figure 1. Best change from baseline based on RECIST 1.1



Safty:

- 33 patients(89.19%) had grade 1-3 treatment-related adverse events, but no serious adverse events were observed.
- Grade 3 adverse events included neutrophil count decreased(5.41%), white blood cell count decreased(5.41%), platelet count decreased(2.7%), anemia(2.7%), alanine aminotransferase increased(2.7%), and hyperkalemia(2.7%).

CONCLUSIONS

- Safety and tolerability data are encouraging for Envafolimab in combination with standard chemoradiotherapy regimen for LANPC.
- Preliminary efficacy data align with standard chemoradiotherapy regimen.
- Long-term efficacy will be followed continuously in this ongoing trial.

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