High Complete Response Rate With TNB-486 in Relapsed/Refractory Follicular Lymphoma: Interim Results From an Ongoing Phase 1 Study

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Background
- T-cell-engager (TCE) is a novel, fully human IgG4 CD19xCD3 monoclonal antibody (mAb) being developed to target CD19-positive follicular lymphoma (FL), a B-cell malignancy, and the treatment of choice for FL is rituximab (RTX) with or without chemotherapy.
- CD19 is a pan-B-cell marker expressed on most B-cell malignancies and is a central component of the B-cell receptor complex.
- TCEs are a new class of T-cell engagers, which can activate T-cells (through a Fc tail mimetic) when conjugated to a CD19-directed mAb.
- CD19-directed CAR-Ts have been shown to be effective in CD19-positive B-cell malignancies, but they are not indicated for CD19-negative disease.

Objectives
- To report interim data on the safety, tolerability, and preliminary efficacy of TNB-486.
- To identify optimal doses (ODs).

Methods
- 13 patients with relapsed/refractory FL were enrolled in the study.
- TNB-486 was administered as a 30 µg priming dose followed by escalating doses of 270 µg, 900 µg, 2400 µg, and 7200 µg every 2 weeks.
- Efficacy was evaluated using the Response Evaluation Criteria in Lymphoma (RECIL) criteria.

Results
- 75% of patients responded to treatment, with 30% achieving complete response (no signs of active tumor on imaging).
- The safety profile was favorable, with only 1 patient discontinuing treatment due to COVID-19 infection, unrelated to treatment.
- TNB-486 demonstrated a favorable safety profile with AEs affecting ≥20% of patients that were grade 1–2.
- No infections were reported.

Conclusion
- TNB-486 has shown promising efficacy and safety in patients with relapsed/refractory FL, warranting further investigation in the phase 2 trial.

Plain language summary
Follicular lymphoma is a type of cancer that affects lymph nodes, and it is usually considered incurable. The treatment for this disease is currently limited, and patients often experience side effects from the medications used. TNB-486 is a new type of medication called a T-cell engager, which can activate the immune system to fight the cancer. In this study, 13 patients with follicular lymphoma were treated with TNB-486, and 75% of them showed a good response to the treatment, with 30% achieving a complete response. The treatment was generally safe, with only one patient discontinuing due to COVID-19, unrelated to the treatment. These results suggest that TNB-486 may be an effective treatment option for patients with follicular lymphoma.