542 RANDOMIZED TRIAL OF TUMOR LYSATE PARTICLE ONLY VACCINE VS. TUMOR LYSATE PARTICLE-LOADED, DENDRITIC CELL VACCINE TO PREVENT RECURRENCE OF RESECTED STAGE III/IV MELANOMA: 36-MONTH ANALYSIS

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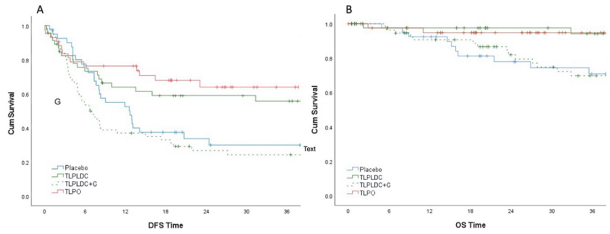
Background The tumor lysate, particle-loaded, dendritic cell (TLPLDC) vaccine is an autologous tumor vaccine that decreased recurrence in stage III/IV melanoma when granulocyte-colony stimulating factor (G-CSF) was not used to harvest the dendritic cells in a randomized phase 2B adjuvant trial.[1]The tumor lysate (TL) particle only (TLPO) vaccine utilizes a similar mechanism, but with autologous TL-loaded yeast cell wall particles; this eliminates the need for dendritic cell (DC) collection and ex-vivo loading and reduces production costs and time. The TLPO vaccine was compared to TLPLDC in an embedded bridging portion of the trial. Here, we examine 36-month outcomes of the ongoing randomized, double-blind phase 2 trial in patients (pts) with resected stage III/IV melanoma.

Methods Pts were randomized 2:1 to receive TLPO or TLPLDC as a continuation of a previously established clinical trial comparing TLPLDC versus placebo. The TLPLDC group was analyzed separately based on use (or not) of G-CSF for collection of DC. Safety was measured by the Common Terminology Criteria for Adverse Events (CTCAE). Kaplan-Meier and log-rank analysis was used to compare 36-month disease-free survival (DFS) and overall survival (OS) in the intention-to-treat (ITT) main arms as well as pre-specified subgroups.

Results A total of 187 pts were randomized with 41, 47, 56, and 43 pts enrolled in the placebo, TLPLDC without G-CSF (TLPLDC), TLPLDC with G-CSF (TLPLDC+G), and TLPO arm, respectively. Pts randomized to the TLPO arm were more likely to have stage IV melanoma (22.0% for placebo, 20.4% for TLPLDC and TLPLDC+G, and 44.2% for TLPO; $p = 0.002$) and to receive prior immunotherapy (36.6% for placebo, 39.8% for both TLPLDC and TLPLDC+G, and 83.7% for TLPO; $p < 0.001$). Grade 3+ adverse events were not significantly different between arms. In the ITT analysis, 36-month DFS was 30.0% for placebo, 55.8% for TLPLDC, 24.4% for TLPLDC+G, and 64.0% for TLPO ($p < 0.001$). OS at 36 months was 70.9% for placebo, 94.2% for TLPLDC, 69.8%% for TLPLDC+G, and 94.8% for TLPO ($p = 0.011$) (figure 1).



Abstract 542 Figure 1 Kaplan-Meier curves demonstrating DFS (A) and OS (B) between Placebo (n=41), TLPLDC (n=47), TLPLDC+G (n=56), and TLPO (n=43)

Conclusions The TLPO and TLPLDC (without G-CSF) vaccines improved 36-month DFS and OS in this randomized phase 2 trial. The efficacy of the TLPO and TLPLDC vaccines will be confirmed in a phase III trial in resected Stage III/IV melanoma pts.

Trial Registration NIH, clinicaltrials.gov, NCT02301611

REFERENCES

1. O'Shea AE, Chick RC, Clifton GT, et al. The effect of pretreatment with G-CSF prior to dendritic cell collection during the phase IIb trial of an autologous DC-based vaccine for advanced, resectable melanoma. Presented at: Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting & Preconference Programs (SITC 2020); November 11–14, 2020. Abstract 310. J Immunother Cancer. 2020;8(Suppl 3):A656–A959.

Ethics Approval The clinical trial protocol was approved by the Western Institutional Review Board (2014–1932). All participants provided informed consent prior to enrollment in the trial.

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