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. 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 44.2% 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).

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

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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