CT150: Initial analysis of open-label administration of autologous tumor lysate + dendritic cells vaccine (TLPLDC) in melanoma patients who recurred during a phase IIb adjuvant vaccine trial

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BACKGROUND

Melanoma has proven to be immunogenic, and many novel treatment strategies targeting this cancer have been initiated. Additionally, patients with stage III-IV melanoma have a high risk of recurrence after resection despite standard of care therapies. We are conducting a prospective, randomized, double-blind, placebo-controlled phase IIb trial of an autologous tumor lysate, particle loaded, dendritic cell (TLPLDC) vaccine to prevent recurrence in these high risk patients. Patients who recur on study are offered open-label TLPLDC vaccination +/- other standard of care systemic therapies as indicated. Here, we report the initial outcomes of the open label patients.

METHODS

Patients with resected stage III/IV melanoma were randomized to TLPLDC vs. empty YCWP loaded dendritic cells in a 2:1 fashion. TLPLDC is created by in vitro loading of dendritic cells by YCWPs derived from *Saccharomyces cerevisiae* containing autologous tumor lysate, then given as 1-1.5x10^6 TLPLDC inoculations. Patients who recurred on the trial (primary endpoint) were offered open label TLPLDC vaccination along with standard of care therapy as determined by the patient's treatment team. Disease status is measured by RECIST criteria on imaging as ordered by the primary physician.

Figure 1

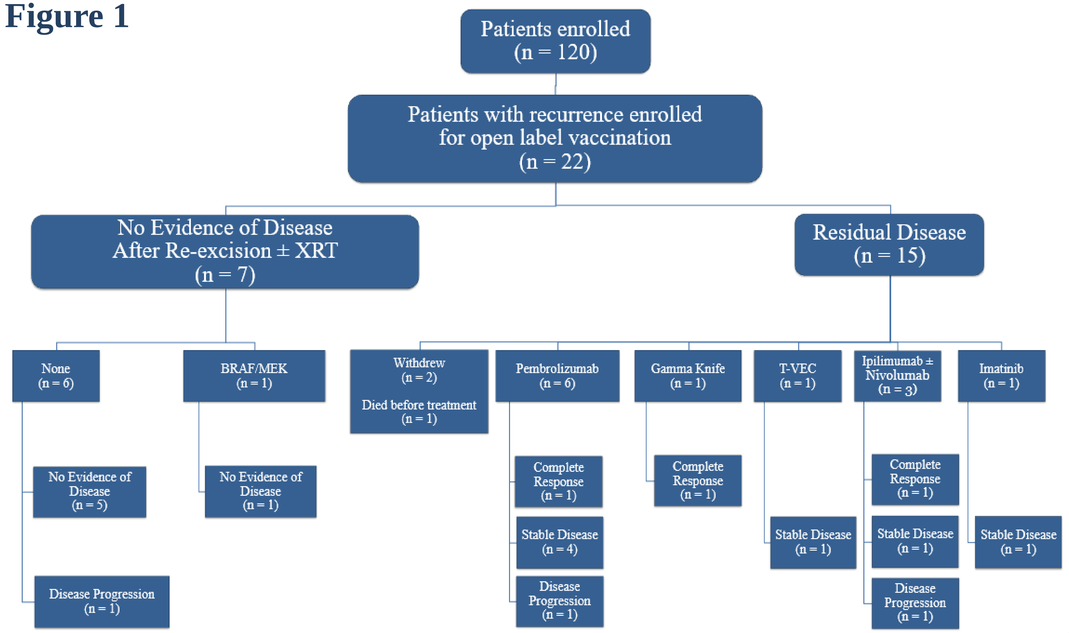


Figure 2

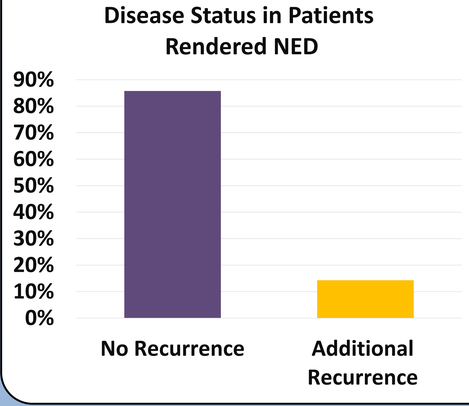
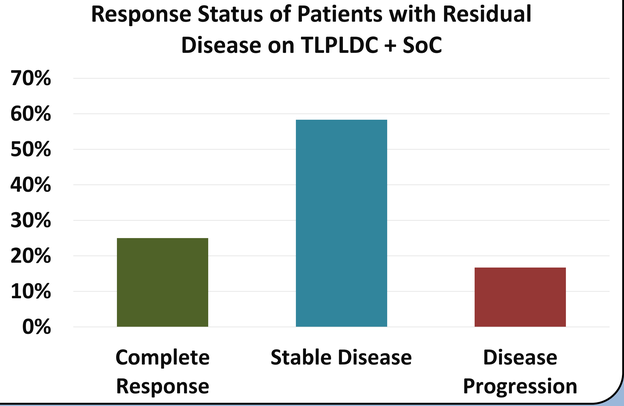


Figure 3



RESULTS

To date, twenty-two patients have received active open-label vaccine after recurrence with a median of 7.1 months follow-up since initiating open-label vaccine therapy **(Figure 1).** Seven patients had no evidence of disease after re-excision ± XRT. One of these patients was also treated with BRAF/MEK inhibition. Of the seven patients, only one has recurred at a median follow-up of 12.5 months (**Figure 2**). The remaining 15 patients were not surgically resectable and received systemic standard of care therapy (per treating physician) + adjuvant TLPLDC for their residual metastatic disease. Of these 15 patients, two withdrew and one died prior to vaccination leaving 12 evaluable patients. Of these 12 patients, six were treated with pembrolizumab, one with gamma knife therapy, one with talimogene laherparepvec (T-VEC), three with ipilimumab ± nivolumab, and one with imatinib. Three patients have shown a complete response (median follow-up = 8.5 mos), seven have stable disease, and two have disease progression **(Figure 3).** Interestingly, one patient now with a complete response had disease progression prior to initiating ipilimumab and nivolumab in conjunction with the TLPLDC vaccine.

CONCLUSION

On initial analysis, open label administration of the TLPLDC vaccine after recurrence may have benefit when combined with standard of care therapy in the adjuvant setting and in patients with measurable metastatic disease. Additional follow-up and controlled trials are needed to confirm benefit in these settings.

Disclosures: GE Peoples receives compensation from Orbis Health Solutions.