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# Clinical efficacy of vaccination with the autologous tumor lysate particle loaded dendritic cell (TLPLDC) vaccine in metastatic melanoma.

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Abstract Disclosures

## Abstract

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**Background:** The treatment of melanoma has changed drastically with the advent of immunotherapy. The autologous tumor lysate, particle loaded, dendritic cell (TLPLDC) vaccine stimulates T-cells and may work synergistically with other immunotherapies. Here, we describe results in patients (pts) with metastatic melanoma (MM) treated with the TLPLDC vaccine together with other

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approved therapies. **Methods:** The TLPLDC vaccine is created using autologous tumor lysate loaded yeast cell wall particles to prime autologous dendritic cells ex-vivo. 1-1.5x$10^6$ TLPLDCs are given via intradermal injection monthly x 4 followed by boosters at six and nine months (mo). Pts who recurred while enrolled in our adjuvant phase IIb trial of the TLPLDC vaccine and pts with MM with measurable disease enrolled in a separate phase I/IIa trial were offered vaccination of TLPLDC vaccine in an open-label fashion in addition to other approved therapies as determined by their treating physician. Tumor response is measured by RECIST 1.1 criteria. **Results:** To date, 50 pts have been enrolled in the two trials (25 pts in each). Of the 42 pts with measureable disease, 30 pts received at least one dose of the vaccine, 11 progressed prior to vaccine administration, and 1 is pending. 2 pts withdrew at 2 and 7 mo. Of the remaining 28 evaluable pts, 13 pts had progressive disease with a median follow-up (f/u) of 3 (range 0-12) mo, 12 pts had stable disease with a median f/u of 7.5 (range 1-23) mo, 2 pts had a partial response with f/u of 7 and 13 mo, and one pt had a complete response with 18 mo of f/u. Overall, in pts with measureable disease, the disease control rate was 54% (15/28) and objective response rate was 11% (3/28). 8 pts were without measurable disease at enrollment, 3 recurred at a median f/u of 8 mo and 5 remain disease-free at a median of 26 mo f/u. No grade ≥ 3 toxicities were observed with combination TLPLDC vaccination and approved systemic therapies. **Conclusions:** Vaccination with the TLPLDC vaccine in combination with systemic approved therapies in MM pts is well tolerated and may provide clinical benefit in patients with and without measurable disease. Clinical trial information: NCT02678741.



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