

## MENU

[Journal of Clinical Oncology](#) > [List of Issues](#) > [Volume 38, Issue 5 suppl](#) >

## Article Tools

### MELANOMA/SKIN CANCERS

**Multi-institutional, prospective, randomized, double-blind, placebo-controlled phase IIb trial of the tumor lysate, particle-loaded, dendritic cell (TLPLDC) vaccine to prevent recurrence in high-risk melanoma patients: A subgroup analysis.**

[Robert Connor Chick](#), [Mark B. Faries](#), [Diane F. Hale](#), [Phillip M. Kemp Bohan](#), [Annelies Hickerson](#), [Timothy J. Vreeland](#), [John William Myers](#), [Jessica L. Cindass](#), [Tommy A. Brown](#), [John Robert Hyngstrom](#), [James W. Jakub](#), [Jeffrey J. Sussman](#), [Adam C. Berger](#), [Montaser F. Shaheen](#), [G. Travis Clifton](#), [Thomas Wagner](#), [George Earl Peoples](#)

Brooke Army Medical Center, Fort Sam Houston, TX; John Wayne Cancer Institute, Santa Monica, CA; The Univ of Utah, Salt Lake City, UT; Mayo Clinic, Rochester, MN; University of Cincinnati, Cincinnati, OH; Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; University of Arizona Cancer Center, Tucson, AZ; Perseus PCI, Greenville, SC; Cancer Vaccine Development Program, San Antonio, TX

[Show Less](#)

[Abstract Disclosures](#)

Abstract

63

## OPTIONS & TOOLS

[Export Citation](#)

[Track Citation](#)

[Add To Favorites](#)

[Rights & Permissions](#)

## COMPANION ARTICLES

No companion articles

## ARTICLE CITATION

DOI: 10.1200/JCO.2020.38.5\_suppl.63

*Journal of Clinical Oncology* 38, no. 5\_suppl (February 10, 2020) 63-63.

Published online February 04, 2020.

## WHAT'S POPULAR

**Most Read** Most Cited

[Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: ASCO Clinical Practice Guideline Update](#)

Key et al.

[Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American](#)

**Background:** A novel vaccine strategy may prevent recurrence in high-risk melanoma patients (pts). The TLPLDC vaccine uses yeast cell wall particles (YCWP) to load tumor lysate into autologous dendritic cells (DC). In this phase IIb trial of TLPLDC vs. placebo in resected stage III/IV pts, TLPLDC increased 24 month (mo) disease free survival (DFS) in the per treatment (PT) population. Here, we present a 24mo DFS subgroup analysis and estimated overall 36mo DFS. **Methods:** Disease-free pts were randomized 2:1 to the TLPLDC vaccine vs. unloaded YCWP+DC at 0, 1, 2, 6, 12, and 18mo. The protocol was amended to allow concurrent adjuvant checkpoint inhibitor (CPI) therapy once approved. The pre-specified PT population included only pts completing the primary vaccine/placebo series (PVS) at 6 mo. Kaplan-Meier estimates of DFS were used to compare treatment arms by stage (III or IV) and CPI therapy (yes/no) in the ITT and PT populations. **Results:** 144 pts were randomized (103 TLPLDC, 41 placebo); 98 pts (66 TLPLDC, 32 placebo) completed the PVS. There were no clinicopathologic differences between treatment groups. There was no difference in 24mo DFS in stage III pts (n = 112), but in stage IV pts (n = 32), the 24mo DFS was 44% vs 0% (TLPLDC vs placebo) (p = 0.41) in ITT and 73.3% vs. 0% (HR 0.14, p = 0.002) in PT. Stage IV pts were more likely to receive CPI than stage III pts (50% vs. 30%, p = 0.003). There was no difference in 24mo DFS for pts who did not receive CPI (n = 102), but in pts who received CPI (n = 42), the 24mo DFS was 49.3% vs. 31.3% (p = 0.71) in ITT and 68.8% vs. 41.7% (HR 0.46, p = 0.28) in PT, showing a trend toward improved DFS in pts who completed the PVS and received CPI (n = 31). Overall, the 36mo estimated DFS was 34.2% vs. 21.6% (p = 0.89) for ITT and 56.9% vs. 27.9% (p = 0.021) for PT. **Conclusions:** The TLPLDC vaccine improved DFS in patients completing the PVS at 24 and 36 mos, particularly in the resected stage IV subset. The apparent synergistic effect with TLPLDC + CPI will be confirmed in a phase III study evaluating adjuvant TLPLDC + CPI vs. CPI alone in resected stage IV melanoma pts. [Clinical trial information: NCT02301611.](#)

© 2020 American Society of Clinical Oncology

[Society of Clinical Oncology Clinical Practice Guideline](#)

Brahmer et al.

[Prognostic Index for Acute- and Lymphoma-Type Adult T-Cell Leukemia/Lymphoma](#)

Katsuya et al.

[Outpatient Management of Fever and Neutropenia in Adults Treated for Malignancy: American Society of Clinical Oncology and Infectious Diseases Society of America Clinical Practice Guideline Update](#)

Taplitz et al.

[Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update](#)

Hesketh et al.

#### Research Sponsor:

Elios Therapeutics.



#### QUICK LINKS

##### Content

Newest Articles  
Archive

##### Resources

Authors  
Reviewers



#### ASCO FAMILY OF SITES

##### Journals

Journal of Clinical Oncology  
JCO Oncology Practice

##### Education

ASCO eLearning  
ASCO Meetings

Meeting Abstracts

## Journal Information

About

Editorial Roster

Contact Us

Permissions

Subscribers

Institutions

Advertisers

[Submit Your Manuscript](#)

[Subscribe to this Journal](#)

JCO Global Oncology

JCO Clinical Cancer Informatics

JCO Precision Oncology

## Publications

ASCO Educational Book

ASCO Daily News

ASCO Connection

The ASCO Post

JCO OP DAiS

Cancer.Net

## Other Sites

ASCO.org

ASCO Author Services

ASCO Career Center

CancerLinQ

Conquer Cancer Foundation

TAPUR Study



[American Society of Clinical Oncology](#)

2318 Mill Road, Suite 800, Alexandria, VA 22314

© 2020 American Society of Clinical Oncology



[Terms of Use](#) | [Privacy Policy](#) | [Cookies](#)