

Primary overall survival (OS) from OPTiM, a randomized phase III trial of talimogene laherparepvec (T-VEC) versus subcutaneous (SC) granulocyte-macrophage colony-stimulating factor (GM-CSF) for the treatment (tx) of unresected stage IIIB/C and IV melanoma.

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[Melanoma/Skin Cancers](#)

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[Abstract Disclosures](#)

Abstract:

Background: T-VEC is an oncolytic immunotherapy derived from herpes simplex virus type-1 designed to selectively replicate in tumors and produce GM-CSF to enhance systemic antitumor immune responses. OPTiM is a randomized, phase 3 trial of T-VEC or GM-CSF in patients (pts) with unresected melanoma with regional or distant metastases (NCT00769704). OPTiM met the primary endpoint of a statistically significant improvement in durable response rate (DRR) with T-VEC vs GM-CSF (Andtbacka et al. ASCO 2013). The primary analysis of OS is reported here. **Methods:** Key entry criteria were age \geq 18 yrs, ECOG \leq 1, unresectable melanoma stage IIIB/C or IV, injectable cutaneous, SC, or nodal lesions, LDH \leq 1.5X ULN, \leq 3 visceral lesions (excluding lung), none $>$ 3 cm. Pts were randomized 2:1 to intralesional T-VEC (initially \leq 4 mL $\times 10^6$ pfu/mL then after 3 wks, \leq 4 mL $\times 10^8$ pfu/mL Q2W) or SC GM-CSF (125 μ g/m²qd \times 14 days q28d). The primary endpoint was DRR: partial or complete response continuously for \geq 6 mos starting within 12 mos. Responses were per modified WHO by blinded central review. The primary analysis of OS (290 planned events) had 90% power to detect a HR of 0.67 with two sided $\alpha=0.05$. **Results:** 436 pts are in the ITT set: 295 (68%) T-VEC, 141 (32%) GM-CSF. 57% were men; median age was 63 yrs. An increase of

4.4 mos in OS with T-VEC vs GM-CSF was observed ($p=0.051$): HR 0.787 (95% CI: 0.62, 1.00); median (95% CI) OS was 23.3 (19.5, 29.6) mos with T-VEC vs 18.9 (16.0, 23.7) mos with GM-CSF. Objective response rate with T-VEC was 26% (95% CI: 21%, 32%) with 11% CR, and with GM-CSF was 6% (95% CI: 2%, 10%) with 1% CR. DRR for T-VEC was 16% (95% CI: 12%, 21%) and 2% for GM-CSF (95% CI: 0%, 5%), $p<0.0001$. Most common adverse events (AEs) with T-VEC were fatigue, chills, and pyrexia. No \geq grade 3 AE occurred in \geq 3% of pts in either arm.

Conclusions: In pts with unresectable Stage IIIB-IV melanoma, T-VEC demonstrated a significant improvement in the DRR vs GM-CSF with a tolerable safety profile. An improvement in OS approaching statistical significance was seen in the ITT population. Clinical trial information: [NCT00769704](#).