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First real-world data for TIL therapy in patients with metastatic cutaneous melanoma

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Background

Patients with advanced melanoma face limited treatment options after progression on immune checkpoint inhibitors (ICI). Tumor-Infiltrating Lymphocyte (TIL) therapy has shown promising efficacy in this setting, with response rates of 49% in a randomized phase III trial. Based on this trial, hospital exemption (HE) was granted to the Netherlands Cancer Institute (NKI) in January 2023, allowing treatment of advanced melanoma patients with the TIL product TM001. Here, we present real-world data on TM001 therapy in advanced melanoma patients treated within the ongoing HE program.

Methods

Clinical data was retrospectively collected from advanced melanoma patients who received TM001 infusion followed by high-dose interleukin-2 (IL-2), after non-myeloablative lymphocyte-depleting chemotherapy (data cut-off 6 November 2024). We analyzed progression-free survival (PFS), overall survival (OS), objective response rate (ORR) according to RECIST v.1.1 and treatment emergent adverse events (TEAEs).

Results

Fifty patients with advanced melanoma received TM001 therapy within the HE program. All patients experienced disease progression after anti-programmed death-1 (PD-1) containing ICI treatment. Median follow-up was 9.4 months (95% confidence interval = 6.7 – 16.4). Median PFS was 3.5 months after TM001 infusion, ORR was 34% with an 8% complete response rate, and the median OS was 13.9 months. Patients pretreated with anti-PD-1 monotherapy showed an ORR of 39% and patients pretreated with anti-PD-1/anti-CTLA-4 also responded to TM001 therapy, with an ORR of 24% and a similar PFS. Grade ≥3 TEAE were observed for all patients. One serious adverse event, a grade 4 ventricular tachycardia related to IL-2 infusion, was recorded. All patients experienced chemotherapy-related TEAEs, 90% experienced IL-2 related TEAEs and 96% experienced any TEAE related to the TM001 infusion.

Conclusions

Real-world data from advanced melanoma patients treated with TM001 therapy within an HE program, following prior anti-PD-1 containing ICI treatment, confirm efficacy and safety profiles from the previous randomized controlled trial. Notably, patients pretreated with anti-PD-1/anti-CTLA-4 also demonstrate responses to TM001 therapy.

Legal entity responsible for the study

Netherlands Cancer Institute.

Funding

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Disclosure

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