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Outcomes of anti-PD1 antibodies for advanced melanoma in realworld population

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Background: Anti-PD1 antibodies (aPD1s) for advanced melanoma have proven their superiority over chemotherapy and ipilimumab in phase III trials. However, in real-world many patients were not represented in these trials. We report real-world outcomes of aPD1 for advanced melanoma.

Methods: Pts with advanced (non-uveal) melanoma from 2014 to 2016 who received 1st line aPD1 were selected from the Dutch Melanoma Treatment Registry - a population based registry in the Netherlands. Outcomes of pts normally eligible (ELI) for trial participation (ECOG PS of 0-1, no brain metastasis, auto-immune disease, HIV, psychiatric disorder or corticosteroid use) were compared to pts normally non-eligible (N-ELI) for trial participation. Time to event was estimated with Kaplan-Meier method and overall survival (OS) with cox regression analysis.

Results: In total 552 patients with advanced melanoma received 1st line aPD1. Median age was 65yrs (range 21-94). At baseline 28% had elevated LDH, 90% ECOG PS of 0-1, 19% brain metastases, 65% stage IV-M1c disease and 41% had a BRAF mutation. Toxicity grade 3-4 occurred in 68 pts (12.3%). Median follow-up estimated with reverse Kaplan-Meier method was 18.8 mo (95%CI: 18-20). 1- and 2-yr OS (95%CI) was 72% (68-76%) and 59% (55-65%) and median OS was not reached. Median time to next treatment (TTNT) for ELI pts was not reached and TTNT for N-ELI pts was 10.6 mo (95%CI: 8.3-14.7). Median time of treatment duration was 8.8 mo (95%CI: 6.9-10.5) for ELI pts and 5.3 mo (95%CI: 4.1-7.1) for N-ELI pts. 1- and 2-yr OS were respectively 76% (72-81%) and 63% (57-70%) versus 65% (95%CI: 59-72%) and 53 (95%CI: 45-61% (log-rank test p-value: 0.003). Unadjusted hazard ratio (HR) for OS was 1.57 (95%CI: 1.17-2.09) for N-ELI compared to ELI pts and adjusted HR was 1.28 (95%CI: 0.94-1.73). HR for LDH >500 UI/L was 2.10 (95%CI: 1.23-3.58) and HR for BRAF neg. pts 1.74 (95%CI: 1.26-2.41).

Conclusions: Real-world outcomes of $1^{\rm st}$ line aPD1s in patients with advanced melanoma seem to be in accordance to results observed in phase III trials. These data support that N-ELI pts normally not represented in phase III trials may benefit from aPD1 treatment. LDH >500 UI/L and BRAF neg. status were associated with poorer survival.

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