

#P191 | Long-term follow-up (FU) of health-related quality of life (HRQoL) of patients (pts) with melanoma treated with adjuvant nivolumab (NIVO) in a real-world (RW) setting

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PRESERV MEL is a RW study evaluating the long-term effectiveness, safety, and HRQoL of adjuvant NIVO in pts with completely resected stage III or IV melanoma in clinical practice in Belgium and Luxembourg. Results from a 2y interim analysis were previously published.

Pts were enrolled over a 2y period (Jan 2019–Jan 2021) and followed for up to 5y. The primary endpoint is recurrence-free survival (RFS); HRQoL is a secondary endpoint. Kaplan-Meier methods were used to assess RFS. HRQoL was assessed at baseline (BL) and at 3, 6, 9, 12, 18, 24, 36 and 48 months (mo) using the EORTC Quality of Life Questionnaire Core 30 (QLQ-C30), the Functional Assessment of Cancer Therapy—Melanoma (FACT-M), and the EQ-5D-3L. Change from BL was analysed using a mixed model for repeated measures. We report long-term results from the 4y interim analysis (cutoff 31/12/2024) for RFS and HRQoL.

We enrolled 152 pts (125 prospective, 27 retrospective) at 15 hospitals in Belgium and Luxembourg. At analysis (47.5-mo minimum FU), all pts had discontinued adjuvant treatment, and the median time to treatment discontinuation was 11.1 mo (95% CI 10.8–11.3). Pts receiving NIVO achieved a median RFS of 41.5 mo (95% CI 34.1–not estimable). The 3- and 4-y RFS probabilities (95% CI) were 54.1% (45.7–61.7) and 47.9% (39.5–55.9). Completion rates of patient-reported outcomes remained high (94–70%). EORTC QLQ-C30 scores on Global HRQoL, symptom, and functional scales remained stable or improved without exceeding the thresholds of minimally important differences (MID). However cognitive function continued to decline slightly from BL to 4y FU, without the mean values exceeding the MID. The emotional and functional subscales of the FACT-M returned to BL values. The EQ-5D-3L scores remained stable. No new safety signals were observed. After a minimum FU of 47.5 mo, these results confirm the RW long-term effectiveness and safety of NIVO as adjuvant for pts with completely resected stage III or stage IV melanoma and highlight the dual benefit of disease control and preserved HRQoL. The minor but stable decline in cognitive function deserves further study.