

Long-term real-world (RW) outcomes in patients with advanced melanoma (MEL) treated with ipilimumab (IPI) and non-IPI therapies: IMAGE study

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Background: IPI has shown durable overall survival (OS) in patients (pts) with MEL in clinical trials, but robust RW evidence is lacking. We present long-term RW outcomes from the IMAGE study (NCT01511913) in which pts received IPI and non-IPI therapies.

Methods: IMAGE was a large, multinational, prospective, observational study that enrolled adult pts with MEL treated with IPI or non-IPI from June 2012 to March 2015 and included >3 years of follow-up. Adjusted OS curves were based on multivariate Cox regression models by adjusting for covariate effects. Progression-free survival (PFS) was analysed using Kaplan-Meier methods. Patients self-administered the EORTC QLQ-C30, a validated, cancer-specific, health-related quality of life (QoL) questionnaire. **Results:** Of 1356pts, 1094 (81%) received IPI and 262 (19%) received non-IPI as index therapy. In all pts, median age was 64 years, 60% were male, 78% were from the EU, median time on study was 6months, and 78% were pre treated (received ≥2 lines of therapy). In the IPI cohort, 780 pts (71%) remained on IPI and 314 (29%) switched to non-IPI. In the non-IPI cohort, 205 pts (78%) remained on non-IPI and 57 (22%) switched to IPI. Among 1151 pts who received IPI, 26% reported grade 3 treatment related adverse events (AEs); most AEs occurred during year 1. The 3-year OS rates were 28% in the IPI and 25% in the non-IPI cohorts. In pre treated pts, OS rates were 25% in the IPI and 23% in the non-IPI cohorts. However, in treatment-naïve pts, the OS rate in the IPI cohort was 40% compared with 33% in the non-IPI cohort, although the small sample size limits interpretation. Median PFS was 3months in both the IPI and non-IPI cohorts. Completion rates for EORTC QLQ-C30 Global Health Status (GHS) score were 58%–80%. No major differences were observed in changes from baseline for EORTC QLQ-C30 GHS scores between the IPI and non-IPI cohorts, with similar trends of initial worsening and subsequent improvement. **Conclusions:** Long-term, RW outcomes from IMAGE were consistent with those from IPI clinical trials. OS analysis across treatment-naïve and pre treated pts suggested a beneficial role of IPI early in the disease with no detrimental impact on QoL.

Clinical trial identification: NCT01511913.