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Pembrolizumab (pembro) vs placebo as adjuvant therapy for patients (pts) with renal cell carcinoma (RCC): Patient-reported outcomes (PRO) in KEYNOTE-564

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Background

The randomized, double-blind, phase III KEYNOTE-564 (NCT03142334) study met its primary endpoint of disease-free survival with adjuvant pembro vs placebo following surgery in pts with RCC. We present PRO findings for adjuvant pembro vs placebo in KEYNOTE-564.

Methods

PRO were evaluated in all randomized pts with ≥1 dose study treatment and ≥1 completed assessment for the specific outcome. FKSI-DRS and EORTC QLQ-C30 were administered electronically at cycles 1, 5, 9, 13, and 17, treatment discontinuation, 30 days after last dose, and annually thereafter until recurrence or new therapy. Prespecified secondary endpoints included least square (LS) mean change in symptom scores as measured by FKSI-DRS and health-related quality of life as measured by the QLQ-C30 global health status/quality of life (GHS/QoL) and physical functioning (PF) scales from baseline to week 52. CIs were nominal and descriptive.

Results

As of Dec 14, 2020, no pts remained on treatment and median (range) time from randomization to data cutoff date was 24.1 (14.9-41.5) months. Among 496 pts randomized to pembro and 498 pts to placebo, >90% completed the FSKI-DRS and QLQ-C30 at baseline and >60% completed each instrument at week 52. LS mean change in FKSI-DRS score was −1.12 (95% CI, −1.53-−0.71) with pembro vs −0.45 (95% CI, −0.84-−0.05) with placebo; both were below the threshold of ≥3 for clinically meaningful change in FKSI-DRS. LS mean change in QLQ-C30 GHS/QoL score was −4.25 (95% CI, −6.32-−2.19) with pembro vs −1.68 (95% CI, −3.69-0.32) with placebo. LS mean change in QLQ-C30 PF score was −1.81 (95% CI, −3.19-−0.43) with pembro vs −0.90 (95% CI, −2.23-0.44) with placebo. Mean score change for both arms in both scales was below the clinically meaningful change threshold of ≥10 for QLQ-C30. Health-related QoL and symptom scores were maintained across all evaluated time points.

Conclusions

No clinically meaningful changes from baseline in health-related QoL or symptom scores were observed with adjuvant pembro or placebo. These scores remained stable over time. PRO findings suggested that adjuvant pembro was tolerable from a pt perspective.

Clinical trial identification

NCT03142334.

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Legal entity responsible for the study

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