

# Which of your RCC patients at increased risk of recurrence are suitable for post-nephrectomy adjuvant treatment?



KEYTRUDA® (pembrolizumab) as monotherapy is indicated for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.<sup>1</sup>

## KEYNOTE-564 Pre-specified increased disease risk categories<sup>2\*</sup>

Intermediate-high risk:	High risk:	M1 NED
pT2 with Grade 4 or sarcomatoid, N0, M0	pT4, any grade, N0, M0	M1
pT3, any grade, N0, M0	Any pT, any grade with node positive, M0	No evidence of disease (NED) after resection of oligometastatic sites ≤1 year from nephrectomy

## KEYNOTE-564 study design<sup>2</sup>

**Randomised double blinded phase 3 trial in patients with resected clear cell renal cell cancer with increased risk of recurrence.**

Patients were randomised 1:1 (N=994), KEYTRUDA 200 mg IV Q3W (n=496), placebo (saline solution) Q3W (n=498).

Primary end point was investigator assessed disease free survival (DFS). Primary endpoint was met, DFS at 24 months, 77.3% vs. 68.1%, HR 0.68, p=0.002, 95% [CI] 0.53-0.87. The most common adverse events for pembrolizumab treated patients were fatigue (29.7%), diarrhoea (25.4%) and pruritus (22.7%).

\*Risk categories in KEYNOTE-564 were defined by pathological TNM and Fuhrman grading status.<sup>2</sup>

Abbreviations: IV, intravenous; RCC, renal cell carcinoma; mg, milligram; Q3W, once every three weeks M0 = without distant metastases; M1 = with distant metastases; N0 = without nodal involvement; NED = no evidence of disease

**Refer to Summary of Product Characteristics (SmPC) before prescribing.  
Please select the prescribing information for your region:**



This material is for healthcare professionals only

### References:

1. KEYTRUDA® (pembrolizumab). Summary of Product Characteristics
2. Choueri TK et al. N Engl J Med. 2021;385(8):683–694.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme (UK) Limited (Tel: 0208 154 8000)