

➔ UROTHELIAL CARCINOMA

TARGETING PD-1 IN
ADVANCED DISEASE

Data from the KEYNOTE-012 phase Ib study demonstrate that pembrolizumab, an antibody targeting programmed cell death protein 1 (PD-1), has antitumour activity and an acceptable safety profile in patients with advanced urothelial carcinoma.

Several antibodies targeting PD-1 or its ligands are being studied for the treatment of urothelial cancer. Atezolizumab, which targets PD-L1, has been approved for use in patients whose disease progresses after platinum treatment. The phase Ib KEYNOTE-012 study tests pembrolizumab in patients with advanced disease of various origins and includes one cohort with locally advanced or metastatic urothelial cancer. A total of 33 patients who had $\geq 1\%$ PD-L1 expression in their tumour were enrolled in this cohort. Treatment consisted of 10 mg/kg intravenous pembrolizumab every 2 weeks for a maximum of 24 months.

The final analysis was performed on data from 27 patients. With a median treatment duration of 71 days (range 1–708 days) and a median follow-up period of 13 months (range 1–26 months), 26% of patients had an overall response according to RECIST 1.1 (three patients had a complete response and four patients had a partial response; $P = 0.0147$). In addition, four patients had stable disease. The median response duration was 10 months, three responses lasted > 12 months and two complete responses were ongoing at the data cut-off point. Median overall survival was 13 months (95% CI 5–20 months). Five patients and 15 patients had grade 3 or grade 1–2 treatment-related adverse events, respectively.

Clemens Thoma

ORIGINAL ARTICLE Plimack, E. R. *et al.* Safety and activity of pembrolizumab in patients with locally advanced or metastatic urothelial cancer (KEYNOTE-012): a non-randomised, open-label, phase 1b study. *Lancet Oncol.* [http://dx.doi.org/10.1016/S1470-2045\(17\)30007-4](http://dx.doi.org/10.1016/S1470-2045(17)30007-4) (2017)