**BACKGROUND**

Pembrolizumab is approved in 25 global regions for treatment-naive metastatic urothelial carcinoma following progression during or after platinum-based chemotherapy. It is currently approved in over 30 countries in 87% of countries totaling patients with advanced urothelial carcinoma.

On July 1, 2017, the Committee for Medicinal Products for Human Use also recommended approval for this indication.

**KEYNOTE-045**: phase 3 trial of pembrolizumab versus investigator’s choice of chemotherapy (paclitaxel, docetaxel, or vinflunine) in patients with advanced urothelial carcinoma following progression during or after platinum-based chemotherapy.

**Objective**: This trial was prematurely stopped after a planned interim analysis demonstrated statistically significant longer overall survival (OS) with pembrolizumab versus chemotherapy (median follow-up, 11.2 months).

**METHODS**

**Randomization**: Randomized 270 patients to pembrolizumab; 272 patients to investigator’s choice of chemotherapy (paclitaxel, docetaxel, or vinflunine).

**Endpoints**: OS and safety.

**Result**: Pembrolizumab continues to demonstrate a better safety profile than chemotherapy. No new drug-related deaths were reported.

**CONCLUSIONS**

Pembrolizumab continues to be compared with investigator's choice of chemotherapy. In a subgroup analysis, OS benefit with pembrolizumab versus chemotherapy for patients with advanced urothelial carcinoma after failure of platinum-based therapy was seen.

**Supporting Information**


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