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Expanding Immunotherapy Options for Bladder Cancer

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Keywords: Bladder cancer; carcinoma

Commentary on:

Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma

J. Bellmunt, R. de Wit, D.J. Vaughn, Y. Fradet, J.-L. Lee, L. Fong, N.J. Vogelzang, M.A. Climent, D.P. Petrylak, T.K. Choueiri, A. Necchi, W. Gerritsen, H. Gurney, D.I. Quinn, S. Culine, C.N. Sternberg, Y. Mai, C.H. Poehlein, R.F. Perini, and D.F. Bajorin, for the KEYNOTE-045 Investigators*

New Engl. J. Med. 2017 Feb 17 doi: 10.1056/NEJMoa1613683

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Summary

KEYNOTE-045 was a phase 3 multicenter open-label randomized trial of the PD-1 inhibitor pembrolizumab versus second line chemotherapy in patients with advanced urothelial cancer. It included patients previously treated for advanced disease with a platinum-containing regimen as well as those who recurred within 12 months of receiving perioperative chemotherapy for muscle-invasive disease. To be eligible, patients had to have a good ECOG performance status (PS score of 0 or 1). Patients with an ECOG PS score of 2 were allowed only if they had none of the other three Bellmunt risk factors (hemoglobin under 10 g/dL, liver metastasis or last chemotherapy within the past 3 months) [1].

The trial randomized patients in a 1:1 ratio to pembrolizumab at a dose of 200 mg every 3 weeks or one of 3 single-agent chemotherapy regimens (paclitaxel, docetaxel or vinflunine), at the investigator's discretion. The co-primary endpoints were overall survival (OS) and progression-free survival (PFS) in the intention-to-treat population. PD-L1 expression was assessed on new or archival tissue by immunohistochemistry with the 22C3 assay; samples were considered positive if the total PD-L1 expression on tumour and immune cells exceeded 10%.

Overall, 542 patients were enrolled over one year, including 270 in the pembrolizumab group and 272 in the chemotherapy group. The groups were well-balanced and had a high rate of visceral involvement (89.2% and 86% for pembrolizumab and chemotherapy, respectively). Few patients had no Bellmunt risk

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