PMEBRIZUMAB WITH CHEMORADIOThERAPY IN MUSCLE INVASIVE BLADDER CANCER: A PLANNED INTERIM ANALYSIS AND EFFICACY OF THE PCR-MIB (ANZUP 1502) PHASE II TRIAL

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1. METHODS

- Background: A randomized Phase II study examining treatment outcomes of pembrolizumab and cisplatin chemotherapy in patients with muscle invasive bladder cancer. This trial was conducted in collaboration with the Centre for Biostatistics and Clinical Trials (BaCT) at the University of Sydney.

- Treatment and endpoints: Patients were randomized to either pembrolizumab plus cisplatin (P + C) or cisplatin alone (C). The primary endpoint was objective response rate at 16 weeks post-CRT.

- Treatment regimen: Pembrolizumab was administered as 200mg IV every 3 weeks for 7 cycles, in combination with cisplatin 35mg/m² weekly for 6 cycles.

- Follow-up: Follow-up visits were scheduled at weeks 19 and 31, and every 3 months thereafter.

- Adverse events: Adverse events were monitored using the CTCAE v5.0.

2. RESULTS

- Objective response rates: The overall response rate was 70% in the P + C arm and 20% in the C arm.

- Safety: There were no unexpected toxicities, and the treatment was well tolerated.

3. DISCUSSION

- The results support the use of pembrolizumab plus cisplatin as a promising treatment option for patients with muscle invasive bladder cancer.

This study is being conducted by ANZUP in collaboration with The Centre for Biostatistics and Clinical Trials (BaCT). J.D. Dick is supported by an Australian NHMRC Practitioner Fellowship (1110130). ANZUP gratefully acknowledges the Australian Government for infrastructure support through Cancer Australia.

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