

CLAIMS

1. Use of Durvalumab or an antigen binding fragment thereof in the manufacture of a medicament for the treatment of a bladder cancer in a subject in need thereof, wherein the durvalumab or the antigen binding fragment thereof is to be administered to the subject in an amount to provide 10 mg/kg Q2W durvalumab or an antigen binding fragment thereof to treat the bladder cancer.
2. The use of claim 1, wherein the subject's bladder cancer is urothelial carcinoma (UC), advanced UC, or metastatic UC.
3. The use of claim 2, wherein the subject's UC is identified as PD-L1-low or PD-L1low/neg for PD-L1 expression.
4. The use of claim 2, wherein the subject's UC is identified as PD-L1-high/positive for PD-L1 expression.
5. The use of claim 1 or claim 2, wherein the subject has previously undergone a first line cancer therapy comprising a platinum drug or a platinum drug in combination with another anti-cancer agent.
6. The use of claim 1, wherein an effective amount of an anti-CTLA4 antibody or an antigen binding fragment thereof is to be further administered to the subject concurrently or at a different time from the administration of the durvalumab or an antigen binding fragment thereof.
7. The use of claim 5, wherein the first line cancer therapy comprises a therapy selected from cisplatin, cisplatin and gemcitabine, cisplatin and methotrexate, vinblastine, ADRIAMYCINTM (doxorubicin), or carboplatin and gemcitabine doublet combination.
8. The use of claim 6, wherein an effective amount of an anti-CTLA4 antibody or an antigen binding fragment thereof is to be co-administered to the subject with bladder cancer at the same time or at a different time as the administration of durvalumab or the antigen binding fragment thereof.

9. The use of claim 8, wherein the anti-CTLA4 antibody or an antigen binding fragment thereof is tremelimumab or an antigen binding fragment thereof.

10. Use of Durvalumab or an antigen binding fragment in the manufacture of a medicament for the treatment of a bladder cancer in a subject in need thereof, wherein the durvalumab or the antigen binding fragment thereof is to be administered to the subject having bladder cancer in an amount to provide 50 to 2000 mg every 2-4 weeks (Q2W to Q4W) of durvalumab or the antigen binding fragment thereof, in combination with tremelimumab or an antigen binding fragment thereof which is to be administered to the subject in an amount of 50 to 150 mg every 2 to 4 weeks to treat the bladder cancer.

11. The use of claim 10, wherein the durvalumab or an antigen binding fragment thereof is to be administered in an amount of 1500 mg every 4 weeks (Q4W) and the tremelimumab or an antigen binding fragment thereof is to be administered in an amount of 75 mg every 4 weeks (Q4W).

12. The use of claim 10, wherein the subject is identified as having a bladder cancer with a reduced or low level of expression of PD-L1 (PD-L1-low), or with negligible to low expression of PD-L1 (PD-L1-low/neg).

13. The use of claim 10, wherein the subject is identified as having a bladder cancer with a high level of expression of PD-L1 (PD-L1-high).

14. The use of either of claims 1 or 10, wherein the bladder cancer is uroethial carcinoma (UC) and/or cancer of bladder-associated structures and tissue comprising ureter, urethra, urachus and/or renal pelvis.