

Why test PD-L1 in bladder cancer?

Fact Sheet



Unmet need in bladder cancer

Bladder cancer is the **9th most common cancer** globally¹

~ **430,000 new cases** were diagnosed worldwide in 2012¹

- Despite advances in treatment, the prognosis for patients with bladder cancer, and in particular advanced or metastatic disease, remains poor²⁻⁴



Anti-PD-1/PD-L1 immunotherapy is an important treatment choice in bladder cancer

- The programmed cell death-1 (PD-1)/ programmed cell death ligand-1 (PD-L1) pathway is an important checkpoint used by tumour cells (TCs) to inhibit anti-tumour responses⁵

Levels of tumour **PD-L1 expression** in bladder cancer **correlate** with **disease severity and outcomes**⁵

- Blockade of the PD-1/PD-L1 pathway with anti-PD-1/PD-L1 immunotherapy has been associated with improved outcomes for patients with urothelial carcinoma (UC)⁵⁻⁹

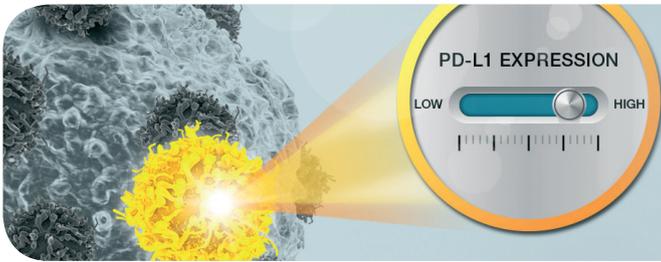


Evidence for PD-L1 IHC testing in bladder cancer

- In patients with UC, anti-PD-1/PD-L1 immunotherapy has been associated with anti-tumour activity⁶⁻⁹

Higher objective response rates have been observed in patients with tumours characterised by **high PD-L1 expression** compared with tumours characterised by low PD-L1 expression⁶⁻⁸

- In a Phase 1/2 study (NCT01693562) in patients with UC, the objective response rate (ORR) with anti-PD-L1 immunotherapy was greater in patients with tumours classified as PD-L1 high ($\geq 25\%$ PD-L1 staining in either TCs or immune cells [ICs])^{7,10}



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- In a Phase 2 study (NCT02108652) in patients with locally advanced or metastatic UC, second-line anti-PD-L1 immunotherapy was associated with a greater ORR in patients with high IC PD-L1 expression ($\geq 5\%$) compared with low/negative PD-L1 expression⁶
- In a Phase 1b study (NCT01772004) in patients with UC receiving immunotherapy with an anti-PD-L1 antibody, 7 out of 8 of the patients with a confirmed objective response had tumours classified as PD-L1 high ($\geq 5\%$ tumour cells expressing PD-L1)⁸
- Similarly, in studies with anti-PD-1 antibodies (NCT02335424 and NCT02387996) in patients with advanced UC, greater clinical benefit was observed in patients whose tumours expressed high levels of PD-L1 versus those with low levels of PD-L1^{11,12}



Implications in the clinic

- Determining tumour PD-L1 expression status in UC tumours can help inform physicians and patients about the likelihood of response to immunotherapy with anti-PD-1/PD-L1 antibodies⁵



Context

- There remains significant unmet need for improving outcomes in patients with UC
- Immunotherapy with anti-PD-1/PD-L1 antibodies has shown efficacy in the treatment of UC
- Tumours expressing high levels of PD-L1 are more likely to respond to anti-PD-1/PD-L1 immunotherapy than those expressing low levels of PD-L1
- Testing tumours for levels of PD-L1 expression can therefore provide important information for physicians when making clinical decisions regarding treatment for patients with UC

References

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