

PD-L1 Expression by IHC

UROTHELIAL CANCER

Overview

- Up to 77,000 patients in the U.S. are expected to be diagnosed with bladder cancer in 2016¹, and the most common type is urothelial carcinoma.²
- The five-year relative survival of patients with metastatic urothelial cancer (mUC) is poor at 5%.³
- Systemic chemotherapy is the standard first-line approach for patients with metastatic urothelial malignancies⁴ and with inoperable locally advanced disease⁵. Although initial response rates are high, the median survival with chemotherapy is approximately 15 months.^{5,6}
- Currently there is no standard therapy for second-line chemotherapy⁴ and thus, for patients who do relapse, the prognosis may be poor. The need to improve outcomes has led to the evaluation of new targeted agents, including immune checkpoint inhibitors.

PD-L1 Expression and Immunotherapy

An ongoing Phase II clinical trial (IMvigor 210 trial) is evaluating second-line treatment of TECENTRIQ™ (atezolizumab) in mUC patients who have progressed after chemotherapy. New data has shown that tumors with high PD-L1 expression levels (IC2/3) correlated with improved overall response rates and median overall survival (OS), and the response to treatment was durable.^{7,8}

The VENTANA® anti-PD-L1 (SP142) IHC assay was recently FDA-approved as a complementary diagnostic assay which may help identify locally advanced or metastatic urothelial cancer patients more likely to respond to treatment with TECENTRIQ™ (atezolizumab).⁹

PD-L1 Status	N (%)	Overall Response Rate, %	Median OS, Months	12-Month OS, %
IC2/3 (≥5%)	100 (32%)	26%	11.4	48%
IC1 (≥1% but <5%)	210 (68%)	10%	6.7	30%
IC0 (<1%)		8%		
All	310 (100%)	15%	7.9%	36%

IC=PD-L1 expression on tumor-infiltrating immune cells, response rates are usually around 10% with second-line standard chemotherapy

Specimen Requirement Options

Global Only

Tissue should be fixed in 10% neutral buffered formalin for a fixative time of at least 6 hours. Fixative times less than 6 hours results in a significant loss of staining intensity. Other fixatives are not recommended.

1) Fixed Paraffin Block with Corresponding H&E

2) Unstained Slides:

- Minimum of 4 slides (include additional slide for H&E)
- Pre-cut slides from paraffin block in 4-5 micron sections and mount on plus (+) slides. Slides should be less than 2 months after sectioning if stored at 15-30°C.



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