Evaluating concordance between PD-L1 immunohistochemistry 28-8 and 22C3 pharmDx assays in metastatic urothelial carcinoma (mUC) in PIVOT-10


1Gastrointestinal Medical Oncology, Department of Pharmacy Practice, Wayne State University College of Medicine, Detroit, MI, USA; 2Vanderbilt-Ingram Cancer Center, Nashville, TN, USA; 3Radiation Oncology, University of California San Francisco, San Francisco, CA, USA; 4Cancer Medicine Department, Institut Gustave Roussy, Hôpital Richelieu, Villejuif, France; 5PharmDx product development, Merck & Co, Kenilworth, NJ, USA; 6Pharmacology Department, San Antonio Memorial Center, San Antonio, TX, USA; 7Medical Oncology, San Francisco Medical Center, San Francisco, CA, USA; 8Pharmacology, Department of Biostatistics, University of California, Berkeley, CA, USA; 9Radiology and Imaging Department, Royal Marsden Hospital Institute of Cancer Research, Sutton, UK.

BACKGROUND

PD-L1 testing in patients with metastatic urothelial carcinoma

- For patients with metastatic urothelial carcinoma (mUC), level of programmed death-ligand 1 (PD-L1) expression is determined by immunohistochemistry (IHC). It is used to guide front-line treatment decisions with immune checkpoint inhibitors (ICIs).

- There are different assays approved for evaluation of PD-L1 expression: 22C3, 28-8, 28-8B, and 28-8C. They are not interchangeable.

RESULTS

- Concordance analysis for PD-L1 CPS as a continuous measure was assessed by Kendall’s tau-b: 0.841 (95% CI: 0.819–0.859).

- Table 2. High level of agreement between the 22C3 and 28-8 assays observed (CPS 10 cut-off; N=259).

- Figure 3. Similar rates of PD-L1 negativity (CPS cut-off <10) using the 22C3 and 28-8 assays (n=259).

- Figure 4. Correlation of CPS scoring (N=259).

CONCLUSIONS

PD-L1 is an important cancer biomarker used to help guide treatment decisions in mUC.

- These data demonstrate high concordance between the 22C3 and 28-8 pharmDx assays for evaluating baseline PD-L1 status, based on CPS, for patients with mUC.

- Both assays demonstrated a similar proportion of PD-L1 low tumors in patients with mUC, suggesting that either assay is suitable for patient selection. PD-L1 negativity rate was similar to that previously reported.

- A high concordation between the assays was observed at a CPS cut-off of <10 vs ≥10.

- Taken together, these results suggest the interchangeability of these assays to define PD-L1 status (using a CPS cut-off of 10) in patients with mUC, potentially simplifying treatment decision making in this patient population.