Appendix V

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| Bajorin,138 2021 | 709 (149 with UTUC) | RCT (CheckMate 274) | Moderate | HR of recurrence (pathologic stage [p or yp] T3-4a, or N+), negative surgical margins, and disease-free within 4 weeks before randomization Allowed cisplatin-based NAC | A. Nivolumab  
B. NU alone: radical NU, placebo | Nivolumab vs. placebo overall sample (bladder UC & UTUC)  
DFS 6 months: 74.9% vs. 60.3%  
Median, months: 20.8 vs. 10.8  
HR 0.70 (98.22% CI 0.55 to 0.90), p<0.001  
by initial tumor origin  
Urinary bladder: HR 0.62 (0.49-0.78)  
Renal pelvis: HR 1.23 (0.67-2.23)  
Ureter: HR 1.56 (0.70-3.48)  
Survival free from recurrence outside the urothelial tract 6 months: 77.0% vs. 62.7%  
Median, months: 22.9 vs. 13.7  
HR 0.72 (0.59 to 0.89)  
Distant MFS 6 months: 82.5% vs. 69.8%  
Median, months: 40.5 vs. 29.5  
HR 0.75 (0.59 to 0.94) | Nivolumab vs. placebo overall sample (bladder UC & UTUC)  
Adverse Events  
any: 98.9% vs. 95.4%  
grade ≥3: 42.7% vs. 7.2%  
Discontinuation due to treatment-related AE: 12.8% vs. 2.0%  
Nivolumab group  
most common treatment-related AE  
any grade  
pruritus: 23.1%  
fatigue: 17.4%  
diarrhea: 16.8%  
grade ≥3  
increased serum lipase: 5.1%  
increased amylase level: 3.7%  
diarrhea: 0.9%  
colitis: 0.9%  
pneumonitis: 0.9%  
Treatment-related deaths  
pneumonitis: n=2  
bowel perforation: n=1 |
| Bellmunt,137 2021 | 809 (54 with UTUC) | RCT (IMvigor010) | Moderate | muscle-invasive, pathologic stage (p or yp stage) T2-4a or N+ tumors | A. Atezolizumab  
B. NU alone: NU with LND, observation | Atezolizumab vs. observation overall sample (bladder UC & UTUC)  
DFS Overall sample (bladder UC & UTUC) 18 months: 51% vs. 49%  
Median DFS, months: 19.4 vs. 16.6  
stratified HR 0.89 (0.74-1.08), log-rank p=0.24  
UTUC patients  
Median DFS, months: 14.2 vs. 28.1  
HR 1.25 (0.57-2.74) | Atezolizumab vs. observation overall sample (bladder UC & UTUC)  
AE, any cause  
Any grade: 94% vs. 79%  
Grade 3-4: 37% vs. 20%  
Serious AE: 31% vs. 18%  
immune mediated AE: 46% vs. 8%  
Atezolizumab group  
treatment-related AEs  
Any grade: 71%  
Grade 3-4: 16%  
Serious AE: 11%  
AE leading to discontinuation: 16%  
AE leading to dose interruption: 33%  
Treatment related death  
Multisystem organ failure 1 |