

# Clinical trials of immune checkpoint inhibition for urothelial carcinoma (advanced) in all type of patients

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## 1 anti-PD-1

Trial	Treatments	Patients	Trials design and methods
<b>nivolumab + CT vs chemotherapy</b>			
<b>CHECKMATE 901A</b> <i>ongoing</i> [NCT03036098] n=NA follow-up:	nivolumab in combination with standard of care chemotherapy versus standard of care chemotherapy	patients with previously untreated inoperable or metastatic urothelial cancer	Parallel groups open-label
<b>pembrolizumab vs chemotherapy</b>			
<b>KEYNOTE-045</b> , 2017 [NCT02256436] n=270/272 follow-up:	pembrolizumab versus investigator's choice of chemotherapy with paclitaxel, docetaxel, or vinflunine	patients with advanced urothelial cancer that recurred or progressed after platinum-based chemotherapy	Parallel groups open-label
<b>Keynote 361 monotherapy</b> [NCT02853305] n=990 follow-up:	pembrolizumab 200 mg every 3 weeks (Q3W) versus chemotherapy alone	patients with histologically or cytologically confirmed unresectable/metastatic urothelial carcinoma	
<b>durvalumab vs nil</b>			
<b>durvalumab phase 1/2</b> n=NA follow-up:	-	patients with locally-advanced or metastatic urothelial carcinoma of the bladder who had progressed while on or after a platinum-containing chemotherapy, including those who progressed within 12 months of receiving therapy in a neoadjuvant or adjuvant setting	Single-arm study
<b>nivolumab vs nil</b>			
<b>Checkmate 275</b> [NCT02387996] n=270 follow-up:	-	patients with metastatic urothelial carcinoma after platinum therapy	Single-arm study
<b>nivolumab vs placebo</b>			
<b>CheckMate 274</b> <i>ongoing</i> [NCT02632409] n=NA follow-up:	Nivolumab versus placebo	patients who have undergone radical surgery for invasive urothelial cancer	Parallel groups double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
<b>CHECKMATE 274A</b> <i>ongoing</i> [NCT02632409] n=NA follow-up: Approximately 5 years	-	Patients With Bladder or Upper Urinary Tract Cancer, Following Surgery to Remove the Cancer	Parallel groups double-blind

## References

### **CHECKMATE 901A, : KEYNOTE-045, 2017:**

Bellmunt J, de Wit R, Vaughn DJ, Fradet Y, Lee JL, Fong L, Vogelzang NJ, Climent MA, Petrylak DP, Choueiri TK, Necchi A, Gerritsen W, Gurney H, Quinn DI, Culine S, Sternberg CN, Mai Y, Poehlein CH, Perini RF, Bajorin DF Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma. N Engl J Med 2017 Feb 17;: [28212060] [10.1056/NEJMoa1613683](https://doi.org/10.1056/NEJMoa1613683)

### **Keynote 361 monotherapy, : durvalumab phase 1/2, :**

#### **Checkmate 275, :**

Sharma P, Retz M, Siefker-Radtke A, Baron A, Necchi A, Bedke J, Plimack ER, Vaena D, Grimm MO, Bracarda S, Arranz J, Pal S, Ohyama C, Saci A, Qu X, Lambert A, Krishnan S, Azrilevich A, Galsky MD Nivolumab in metastatic urothelial carcinoma after platinum therapy (CheckMate 275): a multicentre, single-arm, phase 2 trial. Lancet Oncol 2017;18:312-322 [28131785]

#### **CheckMate 274, :**

### **CHECKMATE 274A, :**

## 2 combination

Trial	Treatments	Patients	Trials design and methods
<b>atezolizumab + CT vs chemotherapy</b> <b>IMVIGOR-130 combination</b> <i>ongoing</i> [NCT02807636] n=NA	-	-	
<b>pembrolizumab + CT vs chemotherapy</b> <b>Keynote 361 combination</b> <i>ongoing</i> [NCT02853305] n=NA follow-up:	first-line pembrolizumab + chemotherapy versus chemotherapy alone investigators choice of cisplatin [70 mg/m2 Q3W] plus gemcitabine [1000 mg/m2 on days 1 and 8 Q3W] OR carboplatin [area under the concentration-time curve 5 Q3W] plus gemcitabine if cisplatin ineligible)	patients with advanced or metastatic urothelial carcinoma (bladder cancer).	

## References

IMVIGOR-130 combination, :

Keynote 361 combination, :

## 3 PD-L1 inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>atezolizumab vs chemotherapy</b>			
<b>IMvigor211 (IC2/3)</b> <i>unpublished</i> [NCT02302807] n=467/464 follow-up:	atezolizumab versus chemotherapy	patients with locally advanced or metastatic urothelial bladder cancer (UBC) who have progressed during or following a platinum-containing regimen	Parallel groups open label global
<b>durvalumab + tremelimumab vs chemotherapy</b>			
<b>DANUBE</b> <i>ongoing</i> [NCT02516241] n=NA follow-up:	durvalumab in Combination with Tremelimumab versus Standard of Care Chemotherapy	Patients With Unresectable Stage IV Urothelial Cancer	open-design
<b>atezolizumab vs control</b>			
<b>IMVIGOR-130 (monotherapy)</b> <i>ongoing</i> [NCT02807636] n=NA follow-up:	Atezolizumab+Gemcitabine+Carboplatin/Cisplatin versus Placebo+Gemcitabine+Carboplatin/Cisplatin	Patients With Untreated Locally Advanced or Metastatic Urothelial Carcinoma	open-design
<b>IMvigor010</b> <i>ongoing</i> [NCT02450331] n=NA follow-up:	Atezolizumab versus Observation	Adjuvant Therapy in Patients With PD-L1 Positive, High Risk Muscle Invasive Bladder Cancer After Cystectomy [IMvigor010]	Open Label
<b>avelumab vs control</b>			
<b>JAVELIN Bladder 100</b> <i>ongoing</i> [NCT02603432] n=NA follow-up:	-	-	open-design
<b>atezolizumab vs nil</b>			
<b>IMvigor210</b> [NCT02951767] n=NA follow-up:	Atezolizumab versus single arm study	Cohort 1 will consist of participants who are treatment-naive and ineligible for cisplatin-containing chemotherapy. Cohort 2 will contain participants who have progressed during or following a prior platinum-based chemotherapy regimen	Single-arm study

## References

### **IMvigor211 (IC2/3), :**

Powles T, Durn I, van der Heijden MS, Loriot Y, Vogelzang NJ, De Giorgi U, Oudard S, Retz MM, Castellano D, Bamias A, Flchon A, Gravis G, Hussain S, Takano T, Leng N, Kadel EE 3rd, Banchereau R, Hegde PS, Mariathasan S, Cui N, Shen X, Derleth CL, Green Atezolizumab versus chemotherapy in patients with platinum-treated locally advanced or metastatic urothelial carcinoma (IMvigor211): a multicentre, open-label, phase 3 randomised controlled trial. *Lancet* 2018;391:748-757 [[29268948](#)]

### **DANUBE, :**

### **IMVIGOR-130 (monotherapy), 0:**

### **IMvigor010, :**

### **JAVELIN Bladder 100, :**

### **IMvigor210, :**

Balar AV, Galsky MD, Rosenberg JE, Powles T, Petrylak DP, Bellmunt J, Loriot Y, Necchi A, Hoffman-Censits J, Perez-Gracia JL, Dawson NA, van der Heijden MS, Dreicer R, Srinivas S, Retz MM, Joseph RW, Drakaki A, Vaishampayan UN, Sridhar SS, Quinn DI, Durn Atezolizumab as first-line treatment in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. *Lancet* 2017;389:67-76 [[27939400](#)]

Entry terms: atezolizumab, MPDL3280A, Tecentriq, RG7446, RG-7446,

## 4 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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