

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
pembrolizumab vs			
KEYNOTE-052 , 2017 [NCT02335424] n=374 follow-up: 5 months (median)	-	cisplatin-ineligible patients with advanced urothelial cancer who had not been previously treated with systemic chemotherapy	Single-arm study open-design
nivolumab + CT vs chemotherapy			
CHECKMATE 901A ongoing [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
pembrolizumab vs chemotherapy			
KEYNOTE-045 , 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
Keynote 361 monotherapy [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	
durvalumab vs nil			
durvalumab phase 1/2 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
nivolumab vs nil			
Checkmate 275 [NCT02387996] n=270 follow-up:	-	patients with metastatic urothelial carcinoma after platinum therapy	Single-arm study
nivolumab vs placebo			

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Trial	Treatments	Patients	Trials design and methods
CHECKMATE 274A <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
CheckMate 274 <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

References

KEYNOTE-052, 2017:

Balar AV, Castellano D, O'Donnell PH, Grivas P, Vuky J, Powles T, Plimack ER, Hahn NM, de Wit R, Pang L, Savage MJ, Perini RF, Keefe SM, Bajorin D, Bellmunt J First-line pembrolizumab in cisplatin-ineligible patients with locally advanced and unresectable or metastatic urothelial cancer (KEYNOTE-052): a multicentre, single-arm, phase 2 study. *Lancet Oncol* 2017;18:1483-1492 [[28967485](#)]

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](#)

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 274A, :

CheckMate 274, :

2 combination

Trial	Treatments	Patients	Trials design and methods
atezolizumab + CT vs chemotherapy			
IMVIGOR-130 combination <i>ongoing</i> [NCT02807636] n=NA	-	-	
pembrolizumab + CT vs chemotherapy			

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Trial	Treatments	Patients	Trials design and methods
Keynote 361 combination <i>ongoing</i> [NCT02853305] n=NA follow-up:	first-line pembrolizumab + chemotherapy versus chemotherapy alone investigators choice of cisplatin [70 mg/m ² Q3W] plus gemcitabine [1000 mg/m ² 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
atezolizumab vs chemotherapy			
IMvigor211 (IC2/3) <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
durvalumab + tremelimumab vs chemotherapy			
DANUBE <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
atezolizumab vs control			
IMVIGOR-130 (monotherapy) [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
IMvigor010 <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
avelumab vs control			
JAVELIN Bladder 100 <i>ongoing</i> [NCT02603432] n=NA follow-up:	-	-	open-design

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Trial	Treatments	Patients	Trials design and methods
atezolizumab vs nil			
IMvigor210 [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

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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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