

Clinical trials of immune checkpoint inhibition for lung cancer (metastatic) in second line

TrialResults-center www.trialresultscenter.org

1 anti-PD-1

Trial	Treatments	Patients	Trials design and methods
nivolumab vs CT			
CheckMate 331 <i>ongoing</i> [NCT02481830] n=NA follow-up:	Nivolumab versus Topotecan Amrubicin	Effectiveness Study of Nivolumab Compared to Chemotherapy in Patients With Relapsed Small-cell Lung Cancer	No masking
nivolumab vs docetaxel			
CheckMate 017 , 2015 <i>unpublished</i> [NCT01642004] n=135/137 follow-up:	Nivolumab 3 mg/kg solution intravenously every 2 weeks until documented disease progression versus Docetaxel 75 mg/m ² solution intravenously every 3 weeks until documented disease progression	patients with advanced SQ NSCLC who fail platinum-based doublet chemotherapy	open
CheckMate 057 , 2015 [NCT01673867] n=292/290 follow-up:	Nivolumab 3 mg/kg solution intravenously every 2 weeks until documented disease progression versus Docetaxel 75 mg/m concentrate for solution for intravenous infusion every 3 weeks until documented disease progression	patients with advanced nonsquamous non-small cell lung cancer (NSCLC) who had progressed on platinum-doublet chemotherapy	Parallel groups open
CheckMate 078 <i>ongoing</i> [NCT02613507] n=NA follow-up:	nivolumab versus Docetaxel	Efficacy Study of Nivolumab Compared to Docetaxel in Subjects Previously Treated With Advanced or Metastatic Non Small Cell Lung Cancer	No masking
pembrolizumab 10mg vs docetaxel			
Keynote 010 10mg , 2015 [NCT01905657] n=346/343 follow-up:	pembrolizumab 10 mg/kg versus docetaxel 75 mg/m every 3 weeks	patients with previously treated non-small-cell lung cancer with PD-L1 expression on at least 1% of tumour cells	open-label
pembrolizumab 2mg vs docetaxel			
Keynote 010 2mg , 2015 [NCT01905657] n=345/343 follow-up:	pembrolizumab 2 mg/kg versus docetaxel 75 mg/m every 3 weeks	patients with previously treated non-small-cell lung cancer with PD-L1 expression on at least 1% of tumour cells	Parallel groups open-label
nivolumab for 1 year vs nivolumab			

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Trial	Treatments	Patients	Trials design and methods
CheckMate 153 <i>ongoing</i> [NCT02066636] n=NA follow-up:	Nivolumab 3 mg/kg solution intravenous infusion over 60 minutes every two weeks until disease progression versus Nivolumab 3 mg/kg solution intravenous infusion over 60 minutes every two weeks until 1 year	patients With Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Progressed During or After Receiving At Least One Prior Systemic Regimen	
durvalumab + osimertinib vs osimertinib			
CAURAL <i>ongoing</i> [NCT02534933] n=NA follow-up:	MEDI4736 & AZD9291 Combination versus AZD9291 Monotherapy (Once daily tablet 80 mg)	patients with Locally Advanced or Metastatic Epidermal Growth Factor Receptor T790M mutation-positive Non-Small Cell Lung Cancer who have received Prior Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy	open label UK
nivolumab vs placebo			
CheckMate 451 <i>ongoing</i> [NCT02538666] n=NA follow-up:	Nivolumab monotherapy Nivolumab and ipilimumab combination therapy versus Placebo	A Study of Nivolumab, or Nivolumab in Combination With Ipilimumab, or Placebo in Patients With Extensive-Stage Disease Small Cell Lung Cancer (ED-SCLC) After Completion of Platinum-based Chemotherapy	Participant, Care Provider, Investi

References

CheckMate 331, :

CheckMate 017, 2015:

Brahmer J, Reckamp KL, Baas P, Crin L, Eberhardt WE, Poddubskaya E, Antonia S, Pluzanski A, Vokes EE, Holgado E, Waterhouse D, Ready N, Gainor J, Arn Frontera O, Havel L, Steins M, Garassino MC, Aerts JG, Domine M, Paz-Ares L, Reck M, Baudelet C, Harbis Nivolumab versus Docetaxel in Advanced Squamous-Cell Non-Small-Cell Lung Cancer. *N Engl J Med* 2015 May 31;: [26028407] [10.1056/NEJMoa1504627](https://doi.org/10.1056/NEJMoa1504627)

CheckMate 057, 2015:

Borghaei H, Paz-Ares L, Horn L, Spigel DR, Steins M, Ready NE, Chow LQ, Vokes EE, Felip E, Holgado E, Barlesi F, Kohlhuf M, Arrieta O, Burgio MA, Fayette J, Lena H, Poddubskaya E, Gerber DE, Gettinger SN, Rudin CM, Rizvi N, Crin L, Blumenschein GR Jr, Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer. *N Engl J Med* 2015 Oct 22;373:1627-39 [26412456] [10.1056/NEJMoa1507643](https://doi.org/10.1056/NEJMoa1507643)

CheckMate 078, :

Keynote 010 10mg, 2015:

Herbst RS, Baas P, Kim DW, Felip E, Prez-Gracia JL, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, de Castro G Jr, Garrido M, Lubiniecki GM, Shentu Y, Im E, Dolled-Filhart M, Garon EB Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. *Lancet* 2015 Dec 18;: [26712084] [10.1016/S0140-6736\(15\)01281-7](https://doi.org/10.1016/S0140-6736(15)01281-7)

Keynote 010 2mg, 2015:

Herbst RS, Baas P, Kim DW, Felip E, Prez-Gracia JL, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, de Castro G Jr, Garrido M, Lubiniecki GM, Shentu Y, Im E, Dolled-Filhart M, Garon EB Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. *Lancet* 2015 Dec 18;: [26712084] [10.1016/S0140-6736\(15\)01281-7](https://doi.org/10.1016/S0140-6736(15)01281-7)

CheckMate 153, :

CAURAL, 0:

CheckMate 451, :

2 combination

Trial	Treatments	Patients	Trials design and methods
nivolumab + ipilimumab vs nivolumab			
Checkmate 032 <i>ongoing</i> [NCT01928394] n=NA follow-up:	nivolumab + ipilimumab combination (N1 + I3 or N3 + I1 Q3W for 4 cycles then N3 Q2W) versus nivolumab ([mg/kg] N3 Q2W)	AdvSCLC pts with progressive disease (PD) after 8805;1 platinum-based chemotherapy, regardless of platinum sensitivity or tumor PD-1 ligand 1 (PD-L1) expression	
nivolumab + ipilimumab vs platinum-based CT			
CheckMate 722 <i>ongoing</i> [NCT02864251] n=NA follow-up:	Nivolumab+Platinum doublet chemotherapy Nivolumab + Ipilimumab versus Platinum doublet chemotherapy	Patients With EGFR Mutation, T790M Negative NSCLC Who Have Failed 1L EGFR TKI Therapy	No masking
durvalumab + tremelimumab vs Standard of Care			
ARCTIC PD-L1 negative, 2018 <i>unpublished</i> [NCT02352948] n=NA follow-up:	combination of MEDI4736 (durvalumab) plus tremelimumab versus Standard of Care	patients with PD-L1 negative Locally Advanced or Metastatic Non Small Cell Lung Cancer who have received at least 2 prior systemic treatment regimens including 1 platinum-based chemotherapy regimen for NSCLC	

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References

Checkmate 032, :

CheckMate 722, :

ARCTIC PD-L1 negative, 2018:

3 PD-L1 inhibitors

Trial	Treatments	Patients	Trials design and methods
atezolizumab vs Best Supportive Care			
IMpower 010 <i>ongoing</i> [NCT02486718] n=NA follow-up:	Atezolizumab versus Best Supportive Care	participants with Stage IB-Stage IIIA non-small cell lung cancer (NSCLC) following resection and adjuvant chemotherapy	No masking
atezolizumab vs docetaxel			
OAK, 2016 [NCT02008227] n=425/425 follow-up: minimum 19 months	atezolizumab versus docetaxel	Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum Therapy	Parallel groups open label

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Trial	Treatments	Patients	Trials design and methods
POPLAR Phase 2 atezolizumab , 2016 [NCT01903993] n=144/143 follow-up:	Atezolizumab versus docetaxel 75 mg/m(2) once every 3 weeks	patients with locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum Th	Parallel groups open label 13 countries in Europe and North America
IMpower 210 ongoing [NCT02813785] n=NA follow-up:	Atezolizumab versus Docetaxel	Non-Small Cell Lung Cancer (NSCLC) After Failure With Platinum-Containing Chemotherapy	Open Label
avelumab vs docetaxel			
JAVELIN Lung 200 ongoing [NCT02395172] n=NA follow-up:	avelumab versus docetaxel	subjects with programmed death ligand 1 (PD-L1) positive, non-small cell lung cancer (NSCLC) after failure of a platinum-based doublet	
durvalumab vs Standard of Care			
ARCTIC PD-L1 positive ongoing [NCT02352948] n=NA follow-up:	durvalumab versus Standard of Care	patients with PD-L1 positive Locally Advanced or Metastatic Non Small Cell Lung Cancer who have received at least 2 prior systemic treatment regimens including 1 platinum-based chemotherapy regimen for NSCLC	

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References

IMpower 010, :

OAK, 2016:

Rittmeyer A, Barlesi F, Waterkamp D, Park K, Ciardiello F, von Pawel J, Gadgeel SM, Hida T, Kowalski DM, Dols MC, Cortinovis DL, Leach J, Polikoff J, Barrios C, Kabbinar F, Frontera OA, De Marinis F, Turna H, Lee JS, Ballinger M, Kowanetz M, He P, Chen Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. *Lancet* 2017;389:255-265 [27979383]

POPLAR Phase 2 atezolizumab, 2016:

Vansteenkiste J Atezolizumab monotherapy vs docetaxel in 2L/3L non-small cell lung cancer: Primary analyses for efficacy, safety and predictive biomarkers from a randomized phase II study (POPLAR) ESMO 2015

Fehrenbacher L, Spira A, Ballinger M, Kowanetz M, Vansteenkiste J, Mazieres J, Park K, Smith D, Artal-Cortes A, Lewanski C, Braiteh F, Waterkamp D, He P, Zou W, Chen DS, Yi J, Sandler A, Rittmeyer A Atezolizumab versus docetaxel for patients with previously treated non-small-cell lung cancer (POPLAR): a multicentre, open-label, phase 2 randomised controlled trial. *Lancet* 2016 Mar 9;: [26970723]

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IMpower 210, :

JAVELIN Lung 200, :

ARCTIC PD-L1 positive, 0:

Entry terms: durvalumab, Imfinzi, durvalumab + tremelimumab , ticilimumab, CP 675, P675 cpd, CP-675, CP-675,206, CP-675206, CP675206, CP 675206,

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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