# Clinical trials of immune checkpoint inhibition for lung cancer (metastatic) in all type of patients

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## 1 anti-CTLA-4

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **ipilimumab + chemotherapy vs placebo + chemotherapy** | | | |
| Reck , 2016<br>[NCT01450761]<br>n=478/476<br>follow-up: | ipilimumab 10 mg/kg plus etoposide and platinum (cisplatin or carboplatin)<br>versus<br>placebo plus etoposide and platinum (cisplatin or carboplatin) | patients with newly diagnosed extensive-stage disease SCLC | Parallel groups<br>double-blind |
| Govindan , 2017<br>[NCT01285609]<br>n=388/361<br>follow-up: | ipilimumab 10 mg/kg + paclitaxel and carboplatin<br>versus<br>placebo + paclitaxel and carboplatin | Patients with stage IV or recurrent chemotherapy-nave squamous NSCLC | Parallel groups<br>double-blind |
| phase 2 (phased ipilimumab) , 2012<br>n=204<br>follow-up: | concurrent ipilimumab (four doses of ipilimumab plus paclitaxel and carboplatin followed by two doses of placebo plus paclitaxel and carboplatin) or phased ipilimumab (two doses of placebo plus paclitaxel and carboplatin followed by four doses of ipilimum<br>versus<br>paclitaxel (175 mg/m(2)) and carboplatin (area under the curve, 6) | Patients with chemotherapy-naive non-small-cell lung cancer | Parallel groups<br>double-blind |



## References


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**Govindan, 2017:**

Govindan R, Szczesna A, Ahn MJ, Schneider CP, Gonzalez Mella PF, Barlesi F, Han B, Ganea DE, Von Pawel J, Vladimirov V, Fadeeva N, Lee KH, Kurata T, Zhang L, Tamura T, Postmus PE, Jassem J, O'Byrne K, Kopit J, Li M, Tschaika M, Reck M Phase III Trial of Ipilimumab Combined With Paclitaxel and Carboplatin in Advanced Squamous Non-Small-Cell Lung Cancer. J Clin Oncol 2017;35:3449-3457 [28854067]

**phase 2 (phased ipilimumab), 2012:**

Lynch TJ, Bondarenko I, Luft A, Serwatowski P, Barlesi F, Chacko R, Sebastian M, Neal J, Lu H, Cuillerot JM, Reck M Ipilimumab in combination with paclitaxel and carboplatin as first-line treatment in stage IIIB/IV non-small-cell lung cancer: results from a randomized, double-blind, multicenter phase II study. J Clin Oncol 2012;30:2046-54 [22547592]

# 2 anti-PD-1

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **nivolumab vs docetaxel** | | | |
| CheckMate 017 , 2015<br>*unpublished*<br>[NCT01642004]<br>n=135/137<br>follow-up: | Nivolumab 3 mg/kg solution intravenously every 2 weeks until documented disease progression<br>versus<br>Docetaxel 75 mg/m2 solution intravenously every 3 weeks until documented disease progression | patients with advanced SQ NSCLC who fail platinum-based doublet chemotherapy | open |
| CheckMate 057 , 2015<br>[NCT01673867]<br>n=292/290<br>follow-up: | Nivolumab 3 mg/kg solution intravenously every 2 weeks until documented disease progression<br>versus<br>Docetaxel 75 mg/m concentrate for solution for intravenous infusion every 3 weeks until documented disease progression | patients with advanced nonsquamous nonsmall cell lung cancer (NSCLC) who had progressed on platinum-doublet chemotherapy | Parallel groups<br>open |
| CheckMate 078 *ongoing*<br>[NCT02613507]<br>n=NA<br>follow-up: | nivolumab<br>versus<br>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<br>[NCT01905657]<br>n=346/343<br>follow-up: | pembrolizumab 10 mg/kg<br>versus<br>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<br>[NCT01905657]<br>n=345/343<br>follow-up: | pembrolizumab 2 mg/kg<br>versus<br>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<br>open-label |
| **nivolumab for 1 year vs nivolumab** | | | |
| CheckMate 153 *ongoing*<br>[NCT02066636]<br>n=NA<br>follow-up: | Nivolumab 3 mg/kg solution intravenous infusion over 60 minutes every two weeks until disease progression<br>versus<br>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** | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| CAURAL *ongoing*<br>[NCT02454933]<br>n=NA<br>follow-up: | MEDI4736 & AZD9291 Combination<br>versus<br>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<br>UK |
| **nivolumab vs platinum-based CT** | | | |
| CheckMate 026 , 2016<br>[NCT02041533]<br>n=271/270<br>follow-up: | Nivolumab solution for Injection 3 mg/kg Intravenous every 2 weeks until disease progression<br>versus<br>platinum-based chemotherapy (administered once every 3 weeks for up to six cycles). | patients with previously untreated advanced non-small cell lung cancer (NSCLC) whose tumors expressed PD-L1 at >5% (>1% ???). Patients with EGFR activating mutations and ALK translocations, which are sensitive to targeted therapy, were excluded. | Parallel groups<br>open design |
| CheckMate 227 (nivolumab alone) *ongoing*<br>n=NA<br>follow-up: | versus | Subjects With Chemotherapy-Nave Stage IV or Recurrent Non-Small Cell Lung Cancer | No masking |
| **pembrolizumab vs platinum-based CT** | | | |
| Keynote 024 , 2015<br>[NCT02142738]<br>n=154/151<br>follow-up: 11.2 months (median) | Pembrolizumab (200 mg, administered as intravenous (IV) infusion on Day 1 of each 21-day cycle for up to 35 cycles or until documented PD<br>versus<br>standard of care (SOC) platinum-based chemotherapies | previously untreated advanced NSCLC with PD-L1 expression on at least 50% of tumor cells and no sensitizing mutation of the epidermal growth factor receptor gene or translocation of the anaplastic lymphoma kinase gene | Parallel groups<br>open label |
| Keynote 042 *ongoing*<br>[NCT02220894]<br>n=NA<br>follow-up: | pembrolizumab<br>versus<br>SOC Treatment (Platinum-based Chemotherapy) | Treatment Nave Subjects With PD-L1 Positive Advanced or Metastatic Non-Small Cell Lung Cancer | Parallel groups<br>open label<br>china |
| **pembrolizumab + platinum-based CT vs platinum-based CT** | | | |
| Keynote 189 , 2018<br>[NCT02578680]<br>n=410/206<br>follow-up: 10.5 mo median | pemetrexed and a platinum-based drug plus 200 mg of pembrolizumab, followed by pembrolizumab for up to a total of 35 cycles plus pemetrexed maintenance therapy<br>versus<br>pemetrexed and a platinum-based drug plus placebo every 3 weeks for 4 cycles, followed by placebo | participants with advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) who have not previously received systemic therapy for advanced disease and without sensitizing EGFR or ALK mutations | Parallel groups<br>double-blind |
| KEYNOTE-021 phase 2 , 2016<br>[NCT02039674]<br>n=60/63<br>follow-up: | 24 months treatment with pembrolizumab (200mg every three weeks)+ CT<br>versus<br>four cycles of carboplatin and pemetrexed (500 mg/m2 every three weeks) | patients with stage IIIB/IV, chemotherapy-naive, nonsquamous non-small-cell lung cancer | Parallel groups<br>open design |

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**CheckMate 078, :**

**Keynote 010 10mg, 2015:**

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**Keynote 010 2mg, 2015:**

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**CAURAL, 0:**

**CheckMate 026, 2016:**

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**Keynote 024, 2015:**

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**KEYNOTE-021 phase 2, 2016:**


# 3 combination

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **nivolumab + ipilimumab vs nivolumab** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Checkmate 032 *ongoing*<br>[NCT01928394]<br>n=NA<br>follow-up: | nivolumab + ipilimumab combination (N1 + I3 or N3 + I1 Q3W for 4 cycles then N3 Q2W)<br>versus<br>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 | |
| **durvalumab + tremelimumab vs platinum-based CT** | | | |
| NEPTUNE *ongoing*<br>[NCT02542293]<br>n=NA<br>follow-up: | MEDI4736 + tremelimumab<br>versus<br>platinum-based SoC chemotherapy | the first-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type advanced or metastatic NSCLC | |
| **nivolumab + ipilimumab vs platinum-based CT** | | | |
| CheckMate 227 (High Tumor Mutational Burden) , 2018<br>[NCT02477826]<br>n=139/160<br>follow-up: | nivolumab plus ipilimumab<br>versus<br>chemotherapy | patients with stage IV or recurrent NSCLC that was not previously treated with chemotherapy and high tumor mutational burden (>=10 mutations per megabase), irrespective of PD-L1 expression level | Parallel groups<br>No masking |
| **durvalumab + tremelimumab vs Standard of Care** | | | |
| ARCTIC PD-L1 negative , 2018 *unpublished*<br>[NCT02352948]<br>n=NA<br>follow-up: | combination of MEDI4736 (durvalumab) plus tremelimumab<br>versus<br>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 | |
| **durvalumab +tremelimumab vs Standard of Care** | | | |
| MYSTIC (combination) *ongoing*<br>[NCT02453282]<br>n=NA<br>follow-up: | MEDI4736 (Durvalumab)+Tremelimumab<br>versus<br>Standard of Care chemotherapy treatment | patients with advanced or metastatic NSCLC in the first-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type locally advanced or metastatic NSCLC | open label<br>Germany |



## References

**Checkmate 032, :**

**NEPTUNE, :**

**CheckMate 227 (High Tumor Mutational Burden), 2018:**

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**ARCTIC PD-L1 negative, 2018:**

**MYSTIC (combination), 0:**

# 4 PD-L1 inhibitors

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **atezolizumab + bevacizumab vs bevacizumab (on top platinum-based CT)** | | | |
| IMpower150 (Teff) , 2018<br>[NCT02366143]<br>n=155/129<br>follow-up: | atezo + bev + C + P<br>versus<br>bev + C + P | chemotherapy-nave patients with Stage IV non-squamous non-small cell lung cancer and expression of a tumour T-effector gene signature (Teff) and EGFR et ALK negative (wild type) | Parallel groups<br>open label |
| IMpower150 (WT) , 2018<br>[NCT02366143]<br>n=356/336<br>follow-up: | atezo + bev + C + P;<br>versus<br>bev + C + P | wild type chemotherapy-nave patients with Stage IV non-squamous non-small cell lung cancer (EGFR et ALK negative) | Parallel groups<br>open label |
| **atezolizumab vs docetaxel** | | | |
| OAK , 2016<br>[NCT02008227]<br>n=425/425<br>follow-up: minimum 19 months | atelozumab<br>versus<br>docetaxel | Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum Therapy | Parallel groups<br>open label |
| POPLAR Phase 2 atezolizumab , 2016<br>[NCT01903993]<br>n=144/143<br>follow-up: | Atezolizumab<br>versus<br>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<br>open label<br>13 countries in Europe and North America |
| **avelumab vs docetaxel** | | | |
| JAVELIN Lung 200 *ongoing*<br>[NCT02395172]<br>n=NA<br>follow-up: | avelumab<br>versus<br>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 placebo** | | | |
| PACIFIC , 2017<br>[NCT02125461]<br>n=473/236<br>follow-up: | Durvalumab (at a dose of 10 mg per kilogram of body weight intravenously) every 2 weeks for up to 12 months, administered 1 to 42 days after the patients had received chemoradiotherapy<br>versus<br>placebo | patients with stage III NSCLC who did not have disease progression after two or more cycles of platinum-based chemoradiotherapy | Parallel groups<br>double-blind |
| NCT02273375 *ongoing*<br>[NCT02273375]<br>n=NA<br>follow-up: | durvalumab (MEDI4736)<br>versus<br>placebo | Adjuvant tteatment In Completely Resected Non-Small Cell Lung Cancer Completely Resected NSCLC | double-blind |
| **atezolizumab vs platinum-based CT** | | | |
| GO29432 *ongoing*<br>[NCT02409355]<br>n=NA<br>follow-up: | - | patients with chemotherapy-naive, Stage IV squamous non-small cell lung cancer | open label |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| IMpower 110 *ongoing*<br>[NCT02409342]<br>n=NA<br>follow-up: | Atezolizumab (MPDL3280A)<br>versus<br>dual regimen of carboplatin or cisplatin plus pemetrexed | chemotherapy-naive patients with Stage IV NSCLC | open label |
| **atezolizumab + platinum-based CT vs platinum-based CT** | | | |
| IMpower 131 *ongoing*<br>[NCT02367794]<br>n=NA<br>follow-up: | Atezolizumab + Nab-paclitaxel + Carboplatin<br>Atezolizumab + Paclitaxel + Carboplatin<br>versus<br>Nab-paclitaxel + Carboplatin | chemotherapy-naive participants with Stage IV squamous NSCLC | No masking |
| **avelumab vs platinum-based CT** | | | |
| JAVELIN Lung 100 *ongoing*<br>[NCT02576574]<br>n=NA<br>follow-up: | avelumab<br>versus<br>platinum-based doublet | a First-line Treatment of Recurrent or Stage IV non-small cell lung cancer with Programmed death ligand 1+ tumors | |
| **durvalumab vs Standard of Care** | | | |
| ARCTIC PD-L1 positive *ongoing*<br>[NCT02352948]<br>n=NA<br>follow-up: | durvalumab<br>versus<br>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 | |
| MYSTIC (monotherapy) *ongoing*<br>[NCT02453282]<br>n=NA<br>follow-up: | durvalumab<br>versus<br>Standard of Care chemotherapy treatment | patients with advanced or metastatic NSCLC in the first-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type locally advanced or metastatic NSCLC | open label<br>Germany |



## References


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**IMpower150 (WT), 2018:**

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**NCT02273375, 0:**

**GO29432, 0:**

**IMpower 110, 0:**

**IMpower 131, :**

**JAVELIN Lung 100, :**

**ARCTIC PD-L1 positive, 0:**

**MYSTIC (monotherapy), 0:**



# 5 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.

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