Clinical trials of immune checkpoint inhibition for melanoma in second line (or later)

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1 anti-CTLA-4

Trial	Treatments	Patients	Trials design and methods
ipi + gp100 vs gp100			
Hodi (ipi + gp100) , 2010 [NCT00094653] n=403/136 follow-up:	Ipilimumab, at a dose of 3 mg per kilogram of body weight, was administered with gp100 every 3 weeks for up to four treatments versus gp100 alone	patients with previously treated metastatic melanoma patients with unresectable stage III or IV melanoma, whose disease had progressed while they were receiving therapy for metastatic disease	Parallel groups open-label
ipilimumab 3 mg/kg vs gp100			
Hodi (ipi alone) , 2010 [NCT00094653] n=137/136 follow-up:	ipilimumab 3mg/kg every 3 weeks up to 4 treatments versus gp100 alone	patients with previously treated metastatic melanoma patients with unresectable stage III or IV melanoma, whose disease had progressed while they were receiving therapy for metastatic disease	Parallel groups open-label

References

Hodi (ipi + gp100), 2010:

Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, Gonzalez R, Robert C, Schadendorf D, Hassel JC, Akerley W, van den Eertwegh AJ, Lutzky J, Lorigan P, Vaubel JM, Linette GP, Hogg D, Ottensmeier CH, Lebb C, Peschel C, Quirt I, Clark JI, Wol Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med 2010;363:711-23 [20525992]

Hodi (ipi alone), 2010:

Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, Gonzalez R, Robert C, Schadendorf D, Hassel JC, Akerley W, van den Eertwegh AJ, Lutzky J, Lorigan P, Vaubel JM, Linette GP, Hogg D, Ottensmeier CH, Lebb C, Peschel C, Quirt I, Clark JI, Wol Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med 2010;363:711-23 [20525992]

2 anti-PD-1

Trial	Treatments	Patients	Trials design and methods
nivolumab vs chemotherapy			

continued...

Trial	Treatments	Patients	Trials design and methods
CheckMate 037 (Weber) , 2015 [NCT01721746] n=272/133 follow-up:	ntravenous infusion of nivolumab 3 mg/kg every 2 weeks until progression or unacceptable toxic eff ects versus investigators choice of chemotherapy (dacarbazine 1000 mg/m every 3 weeks or paclitaxel 175 mg/m combined with carboplatin area under the curve 6 every 3 weeks)	patients with advanced melanoma who progressed after ipilimumab, or ipilimumab and a BRAF inhibitor if they were BRAFV mutation-positive (second-line or later-line treatment)	Parallel groups open-label
pembrolizumab 10mg/kg vs chemotherapy			
KEYNOTE 002 (10mg/kg Q3W) , 2015 [NCT01704287] n=181/179 follow-up:	intravenous pembrolizumab 10 mg/kg every 3 weeks versus investigator-choice chemotherapy (paclitaxel plus carboplatin, paclitaxel, carboplatin, dacarbazine, or oral temozolomide)	patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAFV600 mutation positive, a BRAF inhibitor	Parallel groups open design
pembrolizumab 2mg/kg vs chemotherapy			
KEYNOTE 002 (2mg/kg Q3W) , 2015 [NCT01704287] n=180/179 follow-up:	Pembrolizumab 2 mg/kg IV Q3W versus investigator-choice chemotherapy (paclitaxel plus carboplatin, paclitaxel, carboplatin, dacarbazine, or oral temozolomide)	patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAFV600 mutation positive, a BRAF inhibitor	Parallel groups open design
pembrolizumab 2mg/kg vs pembrolizumab 10mg/kg			
KEYNOTE-001 , 2014 [NCT01295827] n=89/84 follow-up:	intravenous pembrolizumab at 2 mg/kg every 3 weeks versus intravenous pembrolizumab at 10 mg/kg every 3 weeks	patients (aged 18 years) with advanced melanoma whose disease had progressed after at least two ipilimumab doses	Parallel groups open-label

References

CheckMate 037 (Weber), 2015:

Weber JS, D'Angelo SP, Minor D, Hodi FS, Gutzmer R, Neyns B, Hoeller C, Khushalani NI, Miller WH Jr, Lao CD, Linette GP, Thomas L, Lorigan P, Grossmann KF, Hassel JC, Maio M, Sznol M, Ascierto PA, Mohr P, Chmielowski B, Bryce A, Svane IM, Grob JJ, Krackha Nivolumab versus chemotherapy in patients with advanced melanoma who progressed after anti-CTLA-4 treatment (CheckMate 037): a randomised, controlled, open-label, phase 3 trial. Lancet Oncol 2015 Apr;16:375-84 [25795410] 10.1016/S1470-2045(15)70076-8

KEYNOTE 002 (10mg/kg Q3W), 2015:

Ribas A, Puzanov I, Dummer R, Schadendorf D, Hamid O, Robert C, Hodi FS, Schachter J, Pavlick AC, Lewis KD, Cranmer LD, Blank CU, O'Day SJ, Ascierto PA, Salama AK, Margolin KA, Loquai C, Eigentler TK, Gangadhar TC, Carlino MS, Agarwala SS, Moschos SJ, Sos Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE-002): a randomised, controlled, phase 2 trial. Lancet Oncol 2015;16:908-18 [26115796]

KEYNOTE 002 (2mg/kg Q3W), 2015:

Ribas A, Puzanov I, Dummer R, Schadendorf D, Hamid O, Robert C, Hodi FS, Schachter J, Pavlick AC, Lewis KD, Cranmer LD, Blank CU, O'Day SJ, Ascierto PA, Salama AK, Margolin KA, Loquai C, Eigentler TK, Gangadhar TC, Carlino MS, Agarwala SS, Moschos SJ, Sos Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE-002): a randomised, controlled, phase 2 trial. Lancet Oncol 2015;16:908-18 [26115796]

KEYNOTE-001, 2014:

Robert C, Ribas A, Wolchok JD, Hodi FS, Hamid O, Kefford R, Weber JS, Joshua AM, Hwu WJ, Gangadhar TC, Patnaik A, Dronca R, Zarour H, Joseph RW, Boasberg P, Chmielowski B, Mateus C, Postow MA, Gergich K, Elassaiss-Schaap J, Li XN, Iannone R, Ebbinghaus SW Anti-programmed-death-receptor-1 treatment with pembrolizumab in ipilimumab-refractory advanced melanoma: a randomised dose-comparison cohort of a phase 1 trial. Lancet 2014;384:1109-17 [25034862]
10.1016/j.ejca.2015.06.072

3 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.

TrialResults-center is non-profit and self-funded.