Clinical trials of B-Raf enzyme inhibitors for melanoma in all type of patients

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1 B-Raf enzyme inhibitors

Trial	Treatments	Patients	Trials design and methods
paclitaxel, carboplatin, sorafenib tosylate vs carboplatin, paclitaxel			
NCI-2012-02978 *ongoing* [NCT00110019] n=NA follow-up:	-	patients with stage III or stage IV melanoma that cannot be removed by surgery	double-blind
Sorafenib and Carboplatin vs Carboplatin/Paclitaxel			
11718 *ongoing* [NCT00111007] n=NA follow-up:	Sorafenib, 400 mg orally, 2 tablets (200 mg each) bid (bis in die [twice daily]) on Study Days 2 to 19 + Paclitaxel (225 mg/m^2*iv*[*Intravenous*])*and**Carboplatin*(*AUC*[*area under the curve*]6*iv*)*on**Study**Day*1(21*dayspercycle*)*versus* *Carboplatin*/*Paclitaxel*(*C*/*P*)(*Paclitaxel*(225*mg*/*m*^{2}*iv*)*and**Carboplatin*(*AUC*6*iv*)*on**Study**Day*1(21*dayspercycle*)	subjects with unresectable Stage III or Stage IV melanoma who progressed after receiving only one prior therapy containing Dacarbazine (DTIC) on Study Day 1 (21 days per cycle)	double-blind
dabrafenib + trametinib vs dabrafenib			
COMBIE-d [NCT01584648] n=NA follow-up:	-	-	
dabrafenib and trametinib vs dabrafenib monotherapy			
COMBI-D [NCT01584648] n=NA follow-up:	dabrafenib and trametinib versus dabrafenib monotherapy	Subjects with histologically confirmed cutaneous melanoma that is either Stage IIIC (unresectable) or Stage IV, and BRAF V600E/K mutation positive will be screened for eligibility	double-blind
MEK162 binimetinib + LGX818 vs LGX818			
COLUMBUS *ongoing* [NCT01909453] n=NA follow-up:	-	patients with locally advanced unresectable or metastatic melanoma with BRAF V600 mutation	open label
dabrafenib and trametinib vs placebo			
COMBI-AD *ongoing* [NCT01682083] n=NA follow-up:	-	Patients with completely resected, histologically confirmed, BRAF V600E/K mutation-positive, high-risk [Stage IIIa (lymph node metastasis >1 mm), IIIb or IIIc] cutaneous melanoma	double-blind
vemurafenib vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
GO27826 *ongoing* [NCT01667419] n=NA follow-up:	vemurafenib 960 mg twice daily versus Placebo	patients with completely resected, cutaneous BRAF-mutation positive melanoma at high risk for recurrence	double-blind
dabrafenib and trametinib vs vemurafenib			
COMBI-v *ongoing* [NCT01597908] n=NA follow-up:	dabrafenib and trametinib versus vemurafenib	Unresectable or Metastatic BRAF V600E/K Cutaneous Melanoma	
LGX818 encorafenib vs vemurafenib			
COLUMBUS *ongoing* [NCT01909453] n=NA follow-up:	LGX818 300 mg QD versus Vemurafenib 960mg BID	patients with locally advanced unresectable or metastatic melanoma with BRAF V600 mutation	open label

References

NCI-2012-02978, 0:

11718, 0:

COMBIE-d, :

Long GV, Stroyakovskiy D, Gogas H, Levchenko E, de Braud F, Larkin J, Garbe C, Jouary T, Hauschild A, Grob JJ, Chiarion Sileni V, Lebbe C, Mandal M, Millward M, Arance A, Bondarenko I, Haanen JB, Hansson J, Utikal J, Ferraresi V, Kovalenko N, Mohr P, Pro Combined BRAF and MEK inhibition versus BRAF inhibition alone in melanoma. N Engl J Med 2014;371:1877-88 [25265492]

COMBI-D, 0:

Long GV, Stroyakovskiy D, Gogas H, Levchenko E, de Braud F, Larkin J, Garbe C, Jouary T, Hauschild A, Grob JJ, Chiarion Sileni V, Lebbe C, Mandal M, Millward M, Arance A, Bondarenko I, Haanen JB, Hansson J, Utikal J, Ferraresi V, Kovalenko N, Mohr P, Pro Combined BRAF and MEK inhibition versus BRAF inhibition alone in melanoma. N Engl J Med 2014;371:1877-88 [25265492]

COLUMBUS, 0:

COMBI-AD, 0:

GO27826, 0:

COMBI-v, 0:

COLUMBUS, 0:

2 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.