Clinical trials of alirocumab

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
alirocumab vs ezetimibe (on top statin)			
ODYSSEY OPTIONS I n=NA follow-up: 24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg)	
ODYSSEY OPTIONS II n=NA follow-up: 24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg)	
alirocumab vs ezetimibe alone			
ODYSSEY MONO [NCT01644474] n=NA follow-up: 24 wk	Alirocumab 75 mg Q2W versus Ezetimibe 10 mg	hypercholesterolemic patients at moderate cardiovascular risk not receiving statins or other lipid-lowering therapy	double-blind
alirocumab vs placebo (on top statins)			
ODYSSEY Alternative [NCT01709513] n=NA follow-up: 65279;24 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	statin-intolerant patients	double-blind
ODYSSEY COMBO [NCT01644175] n=NA follow-up: 52 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	high cardiovascular risk patients on maximally tolerated statin therapy	double-blind
ODYSSEY COMBO II [NCT01644188] n=NA follow-up: 104 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Ezetimibe 10 mg	high cardiovascular risk patients with inadequately controlled hypercholesterolaemia on maximally tolerated doses of statins	double-blind
ODYSSEY FH 1 [NCT01623115] n=NA follow-up: 78 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
ODYSSEY FH 2 [NCT01709500] n=NA follow-up: 78 wk	Alirocumab 75 mg with potential up-titration to 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	double blind
ODYSSEY HIGH FH [NCT01617655] n=NA follow-up: 5278 wk	Alirocumab 150 mg Q2W versus Placebo	patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy	
ODYSSEY Long-Term , 2015 [NCT01507831] n=1553/788 follow-up: 78 wk	alirocumab 150 mg as a 1-ml subcutaneous injection every 2 weeks for 78 weeks. versus placebo	patients at high risk for cardiovascular events who had LDL cholesterol levels of 70 mg per deciliter (1.8 mmol per liter) or more and were receiving treatment with statins at the maximum tolerated dose (the highest dose associated with an acceptable side-effect profile), with or without other lipid-lowering therapy	
ODYSSEY OUTCOMES , 2018 [NCT01663402] n=9462/9462 follow-up: 2.8 yr (median)	Alirocumab (on top intensive or maximum-tolerated statin therapy) versus placebo	Post-ACS patients (1 to 12 months)with elevated levels of atherogenic lipoproteins despite intensive or maximum-tolerated statin therapy	Parallel groups double-blind 57 countries
alirocumab vs			
CHOICE I *ongoing* [NCT01926782] n=NA	-	-	
CHOICE II *ongoing* [NCT02023879] n=NA	-	-	
NCT01288469 *ongoing* [NCT01288469] n=NA	-	-	

More details and results :

- PCSK9 Inhibitors for cardiovascular prevention in all type of patients at http://www.trialresultscenter.org/go-Q599
- on top statins for cardiovascular prevention in all type of patients at http://www.trialresultscenter.org/go-Q722

References

ODYSSEY OPTIONS I, :

Robinson JG, Colhoun HM, Bays HE, Jones PH, Du Y, Hanotin C, Donahue S Efficacy and safety of alirocumab as add-on therapy in high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg): design and rationale of the ODYSSEY OPTIONS Studies. Clin Cardiol 2014 Oct;37:597-604 [25269777]

Bays H, Gaudet D, Weiss R, Ruiz JL, Watts GF, Gouni-Berthold I, Robinson J, Zhao J, Hanotin C, Donahue S Alirocumab as Add-on To Atorvastatin Versus Other Lipid Treatment Strategies: ODYSSEY OPTIONS I Randomized Trial. J Clin Endocrinol Metab 2015 Jun 1;:jc20151520 [26030325]

ODYSSEY OPTIONS II, :

Robinson JG, Colhoun HM, Bays HE, Jones PH, Du Y, Hanotin C, Donahue S Efficacy and safety of alirocumab as add-on therapy in high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg): design and rationale of the ODYSSEY OPTIONS Studies. Clin Cardiol 2014 Oct;37:597-604 [25269777]

ODYSSEY MONO, :

Roth EM, Taskinen MR, Ginsberg HN, Kastelein JJ, Colhoun HM, Robinson JG, Merlet L, Pordy R, Baccara-Dinet MT Monotherapy with the PCSK9 inhibitor alirocumab versus ezetimibe in patients with hypercholesterolemia: results of a 24 week, double-blind, randomized Phase 3 trial. Int J Cardiol 2014;176:55-61 [25037695]

ODYSSEY Alternative, :

Moriarty PM, Jacobson TA, Bruckert E, Thompson PD, Guyton JR, Baccara-Dinet MT, Gipe D Efficacy and safety of alirocumab, a monoclonal antibody to PCSK9, in statin-intolerant patients: design and rationale of ODYSSEY ALTERNATIVE, a randomized phase 3 trial. J Clin Lipidol 2014;8:554-61 [25499937]

ODYSSEY COMBO, :

Kereiakes DJ, Robinson JG, Cannon CP, Lorenzato C, Pordy R, Chaudhari U, Colhoun HM Efficacy and safety of the proprotein convertase subtilisin/kexin type 9 inhibitor alirocumab among high cardiovascular risk patients on maximally tolerated statin therapy: The ODYSSEY COMBO I study. Am Heart J 2015;169:906-915.e13 [26027630]

Colhoun HM, Robinson JG, Farnier M, Cariou B, Blom D, Kereiakes DJ, Lorenzato C, Pordy R, Chaudhari U Efficacy and safety of alirocumab, a fully human PCSK9 monoclonal antibody, in high cardiovascular risk patients with poorly controlled hypercholesterolemia on maximally tolerated doses of statins: rationale and design of the ODYSSEY COMBO I and II trials. BMC Cardiovasc Disord 2014;14:121 [25240705]

ODYSSEY COMBO II, :

Colhoun HM, Robinson JG, Farnier M, Cariou B, Blom D, Kereiakes DJ, Lorenzato C, Pordy R, Chaudhari U Efficacy and safety of alirocumab, a fully human PCSK9 monoclonal antibody, in high cardiovascular risk patients with poorly controlled hypercholesterolemia on maximally tolerated doses of statins: rationale and design of the ODYSSEY COMBO I and II trials. BMC Cardiovasc Disord 2014;14:121 [25240705]

Cannon CP, Cariou B, Blom D, McKenney JM, Lorenzato C, Pordy R, Chaudhari U, Colhoun HM Efficacy and safety of alirocumab in high cardiovascular risk patients with inadequately controlled hypercholesterolaemia on maximally tolerated doses of statins: the ODYSSEY COMBO II randomized controlled trial. Eur Heart J 2015;36:1186-94 [25687353]

ODYSSEY FH 1, :

Kastelein JJ, Robinson JG, Farnier M, Krempf M, Langslet G, Lorenzato C, Gipe DA, Baccara-Dinet MT Efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy: design and rationale of the ODYSSEY FH studies. Cardiovasc Drugs Ther 2014;28:281-9 [24842558]

ODYSSEY FH 2, :

Kastelein JJ, Robinson JG, Farnier M, Krempf M, Langslet G, Lorenzato C, Gipe DA, Baccara-Dinet MT Efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy: design and rationale of the ODYSSEY FH studies. Cardiovasc

Drugs Ther 2014;28:281-9 [24842558]

ODYSSEY HIGH FH , :

Kastelein JJ, Robinson JG, Farnier M, Krempf M, Langslet G, Lorenzato C, Gipe DA, Baccara-Dinet MT Efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy: design and rationale of the ODYSSEY FH studies. Cardiovasc Drugs Ther 2014;28:281-9 [24842558]

ODYSSEY Long-Term, 2015:

Robinson JG, Farnier M, Krempf M, Bergeron J, Luc G, Averna M, Stroes ES, Langslet G, Raal FJ, Shahawy ME, Koren MJ, Lepor NE, Lorenzato C, Pordy R, Chaudhari U, Kastelein JJ Efficacy and Safety of Alirocumab in Reducing Lipids and Cardiovascular Events. N Engl J Med 2015 Mar 15;: [25773378] 10.1056/NEJMoa1501031

ODYSSEY OUTCOMES, 2018:

Schwartz GG, Bessac L, Berdan LG, Bhatt DL, Bittner V, Diaz R, Goodman SG, Hanotin C, Harrington RA, Jukema JW, Mahaffey KW, Moryusef A, Pordy R, Roe MT, Rorick T, Sasiela WJ, Shirodaria C, Szarek M, Tamby JF, Tricoci P, White H, Zeiher A, Steg PG Effect of alirocumab, a monoclonal antibody to PCSK9, on long-term cardiovascular outcomes following acute coronary syndromes: rationale and design of the ODYSSEY outcomes trial. Am Heart J 2014;168:682-9 [25440796]

CHOICE I , :

ongoing trial NCT01926782

CHOICE II , :

ongoing trial NCT02023879

NCT01288469, :

ongoing trial NCT01288469

Entry terms: alirocumab, REGN727 monoclonal antibody, monoclonal antibody REGN727, SAR236553, Praluent,