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Acute and Stable Ischemic Heart Disease

USE OF HIGH-INTENSITY STATIN THERAPY POST-ACUTE CORONARY SYNDROME IN THE ONGOING ODYSSEY OUTCOMES TRIAL OF ALIROCUMAB, A PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 MONOCLONAL ANTIBODY, VERSUS PLACEBO: INTERIM BASELINE DATA

Poster Contributions
Poster Hall, Hall C
Saturday, March 18, 2017, 9:45 a.m.-10:30 a.m.

Session Title: Advances in Lipid Management
Abstract Category: 3. Acute and Stable Ischemic Heart Disease: Therapy
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Background: Despite intensive statin therapy after acute coronary syndromes (ACS), the risk for recurrent cardiovascular (CV) events remains high and related to low-density lipoprotein cholesterol (LDL-C) levels. The ODYSSEY OUTCOMES trial tests the hypothesis that alirocumab, a fully human monoclonal antibody to proprotein convertase subtilisin/kexin type 9 (PCSK9) that produces substantial and sustained LDL-C reductions, improves CV outcomes after ACS.

Methods: At 1,297 participating sites in 57 countries, 18,536 patients with recent ACS and not at optimal lipid levels (LDL-C≥70 mg/dL or Non-HDL-C≥100 mg/dL or ApoB≥80 mg/dL) despite high-intensity (or maximally tolerated) statin±other lipid modifying therapy have been randomized to receive alirocumab or matching placebo. The interim baseline characteristics of patients at randomization (which is ongoing in China) are described.

Results: Randomization occurred a median (interquartile range) 2.6 (1.7-4.3) months after MI (83%) or unstable angina (17%). The Table outlines selected interim characteristics and treatments. High-intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg daily) was used in 89% at randomization; 94% remained on high-intensity at 12 months. Median baseline LDL-C was 87 (73-104) mg/dL.

Conclusions: ODYSSEY OUTCOMES has randomized a high-risk population on intensive statin and guideline-based therapy and will determine whether adding the PCSK9 antibody alirocumab reduces CV events after ACS.

Interim Data (randomization ongoing in China)	Patients randomized (N=18,536)
Age, years - Median (interquartile range [IQR])	58 (52-65)
Male sex, n (%)	13873 (75)
Region, n (%)	
North America/South America	2871 (15)/2588 (14)
Western Europe/Eastern Europe	4172 (23)/5437 (29)
Asia/Rest of World	1905 (10)/1560 (9)
BMI, kg/m^2 – Median (IQR)	28 (25-31)
Cardiovascular (CV) risk factors, n (%)	
History of hypertension	11877 (64)
History of diabetes mellitus	4501 (24)
Current cigarette smoker	4449 (24)
CV history prior to index event, n (%)	
Myocardial infarction	3652 (20)
Coronary revascularization (PCI and/or CABG)	3719 (20)
Ischemic stroke	484 (3)
Peripheral artery disease	719 (4)
Index ACS – Type and Procedures, n (%)	
STEMI/NSTEMI/Unstable Angina	6329 (34)/ 9027 (49)/3152 (17)
Percutaneous coronary intervention (PCI)	12362 (67)
Coronary artery bypass graft surgery (CABG)	1018 (6)
Selected therapy at randomization, n (%)	
Aspirin	17649 (95)
P_2Y_{12} antagonist	16111 (87)
Beta-blocker	15600 (84)
ACE inhibitor or angiotensin receptor blocker	14354 (77)
Lipid Modifying Therapy, n (%)	
Statin >3 months before index ACS	6064 (33)
Statin (atorva or rosuva, any intensity) at randomization	18036 (97)
Statin (high-intensity=atorva 40-80 mg or rosuva 20-40 mg/day)	16565 (89)
Ezetimibe at randomization	545 (3)
Lipid values at randomization, mg/dL – Median (IQR)	
Low-density lipoprotein (LDL-C)	87 (73-104)
Non-high-density lipoprotein (Non-HDL-C)	115 (99-137)
Apolipoprotein-B (Apo-B)	79 (69-93)