

GAUSS-3: Comparison of PCSK9 Inhibitor Evolocumab Versus Ezetimibe in Statin-intolerant Patients: The Goal Achievement After Utilizing an Anti-PCSK9 Antibody in Statin Intolerant Subjects

Purpose: To compare tolerability and LCL-C lowering of evolocumab, a PCSK9 inhibitor, to ezetimibe, a non-statin cholesterol lowering drug, in statin-intolerant, hypercholesterolemic patients

Trial Design: Double-blinded, randomized, multi-center, phase 3 comparison of evolocumab (self-administered injections totaling 420 mg/month) vs. ezetimibe (pill - 10-mg/day). Before randomization, patients with muscle pain were re-challenged to confirm statin intolerance. LDL-C average was 210 mg/dL. N=218.

Primary Endpoint: change in LDL-C from baseline at weeks 22-24 (mean % change); tolerability

Trial Results – % change in LDL-C	Evolocumab	Ezetimibe	P value
LDL reduction after 24 weeks treatment	-52.8%	-16.7%	<0.001
LDL reduction 22-24 weeks treatment	-54.5%	-16.7%	

42.6% of re-challenged patients had muscle pain with atorvastatin vs. placebo

Conclusions: the non-statin PCSK9 inhibitor significantly reduced LDL-C in muscle-related statin intolerant patients