

EFFICACY AND SAFETY OF EVOLOCUMAB

in Chinese Patients With Primary Hypercholesterolemia and Mixed Dyslipidemia: Primary Results of a Phase 3 Randomized Clinical Trial

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HUA TUO 华佗 Study

A phase 3, randomized (2:2:1:1), double-blind, placebo-controlled 12-week study (NCT03433755)



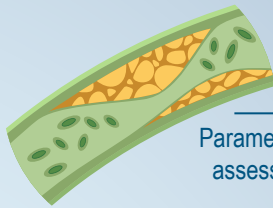
Evolocumab (140 mg SC Q2W and 420 mg SC QM) vs matched placebo

241 Chinese patients aged ≥ 18 years with **primary hypercholesterolemia and mixed dyslipidemia** at different levels of CV risk



Objective

Evaluate the **efficacy and safety** of evolocumab as an add-on to stable optimized statin therapy



Parameters assessed

- LDL-C
- Non-HDL-C
- ApoB
- Lp(a)
- Total cholesterol

Patient Characteristics



Mean (SD) age **60.2 (10.3) years**



Once-daily stable optimized statin therapy \pm ezetimibe



Male **67.6%**



Mean (SD) LDL-C at baseline **116.1 (34.6) mg/dL**



Hypertension **62.2%**



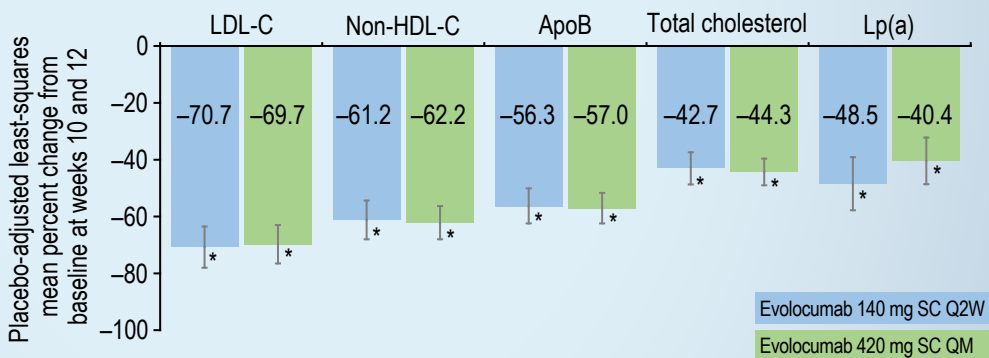
Coronary artery disease **85.9%**
High / very high risk for CVD **92.1%**
 ≥ 2 risk factors for CVD **50.6%**



T2DM **28.6%**

Efficacy

- Significant improvement in LDL-C and other lipids was observed with evolocumab 140 mg Q2W and evolocumab 420 mg QM vs matching placebo
- Reductions in LDL-C were maintained throughout the 12-week study in both evolocumab dosing regimens



Error bars depict 95% CIs.

*All treatment differences (evolocumab vs placebo) in the least-squares mean percent change from baseline for all lipid parameters were statistically significant ($P < 0.0001$).

Safety

Evolocumab vs placebo

≥ 1 TEAEs (patient incidence, %): **54.7% vs 54.9%**

SAEs (patient incidence, %): **4.4% vs 7.3%**

The majority of TEAEs were mild or moderate in severity and no TEAEs led to discontinuation of evolocumab or placebo

Most common TEAEs



URT infection
8.2% vs 8.5%



Hypertension
6.3% vs 6.1%



Hyperuricemia
3.8% vs 0.0%



Hyperbilirubinemia
2.5% vs 4.9%

Conclusion

Evolocumab significantly lowered LDL-C and other lipids, and was safe and well tolerated in Chinese patients with primary hypercholesterolemia and mixed dyslipidemia



Adis

PEER-REVIEWED
FEATURE

ApoB, apolipoprotein B; CV, cardiovascular; CVD, cardiovascular disease; CTCAE, Common Terminology Criteria for Adverse Event; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; Lp(a), lipoprotein(a); QM, once monthly; Q2W, once every two weeks; RCT, randomized clinical trial; SAE, serious adverse event; SC, subcutaneous; SD, standard deviation; TEAE, treatment-emergent adverse event; T2DM, type 2 diabetes mellitus; URT, upper respiratory tract. This graphical abstract represents the opinions of the authors. For a full list of declarations, including funding and author disclosure statements, and copyright information, please see the full text online