AMERICAN COLLEGE of CARDIOLOGY®

Oral PCSK9 Inhibitor MK-0616

Efficacy and Safety of the Oral PCSK9 Inhibitor MK-0616

Phase 2b, Multicenter, International, Double-Blind, Randomized, Placebo-Controlled Trial

OBJECTIVE: To evaluate the efficacy and safety of MK-0616 (an oral PCSK9 inhibitor) in participants with hypercholesterolemia.

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PATIENTS

INCLUSION CRITERIA:

1. Clinical ASCVD plus LDL-C ≥70 mg/dL and ≤160 mg/dL
2. Intermediate or higher risk for ASCVD: No clinical ASCVD with a ≥7.5% 10-year risk of an ASCVD event and/or an ASCVD-risk-equivalent plus LDL-C ≥100 mg/dL and ≤200 mg/dL
3. Borderline risk for ASCVD: No clinical ASCVD with a ≥5.0% and ≤7.5% 10-year risk of an ASCVD event plus LDL-C ≥130 mg/dL and ≤250mg/dL

MK-0616 6 MG (N=77), 12 MG (N=76), 18 MG (N=76) OR 30 MG (N=76) DOSE

VS.

PLACEBO (N=75)

PRIMARY ENDPOINT

PRIMARY ENDPOINT OF PERCENT CHANGE FROM BASELINE IN LDL-C AT WEEK 8 SIGNIFICANTLY REDUCED FOR EACH DOSE OF MK-0616 (6 MG, 12 MG, 18 MG AND 30 MG, RESPECTIVELY) vs. **PLACEBO: –41.2%, –55.7%, –59.1% AND –60.9% (P<0.001 FOR ALL).**

CONCLUSION

Oral inhibition of PCSK9 with MK-0616 in participants with hypercholesterolemia (mean LDL-C 119.5 mg/dL; 38.6% with clinical ASCVD) led to clinically meaningful reductions in LDL-C superior to placebo. All doses were well tolerated with a low incidence of serious AEs or discontinuation of therapy..

Ballantyne CM, Banka P, Mendez G, et al. Efficacy and Safety of the Oral PCSK9 Inhibitor MK-0616: A Phase 2b Randomized Controlled Trial. *J Am Coll Cardiol 2023*;Mar. 6:[Epub ahead of print].

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