EVOLOCUMAB USE IN PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS AND DYSLIPIDEMIA: FINAL RESULTS OF THE OPEN LABEL EXTENSION PERIOD (BEIJERINCK)

Abstract Category: Session 1056 – Cholesterol management: Current Challenges and Future Opportunities

Saturday, May 15, 2021 10:15am-10:25am

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Abstract

Background: People living with human immunodeficiency virus (PLHIV) are at increased risk of atherosclerotic cardiovascular disease. Suboptimal responses to statin therapy in PLHIV may result with antiretroviral therapies (ART).

Methods: This final analysis of a placebo-controlled, double-blind (DB), randomized study (NCT02833844) evaluated the effect of monthly subcutaneous evolocumab 420 mg on low-density lipoprotein cholesterol (LDL-C) during open-label extension (OLE) (week 24 to 52) following the DB period in PLHIV with hypercholesterolemia/mixed dyslipidemia. All patients enrolled had elevated LDL-C or non-high-density lipoprotein cholesterol (non-HDL-C) and were on stable maximally tolerated statin and stable ART. The primary outcome was percent change in LDL-C from baseline to week 24; secondary outcomes included achievement of LDL-C < 70 mg/dL and ≥ 50% LDL-C reduction at week 24. Patient incidence of treatment-emergent adverse events (TEAEs) was also examined.

Results: Of 467 patients randomized in the DB period, 451 (96.6%) completed the OLE. Evolocumab reduction of LDL-C and other lipid parameters was maintained throughout the OLE period (Table). Safety results were comparable to those in other evolocumab studies; infections were similar between placebo and evolocumab during DB and OLE.

Conclusion: Long-term administration of evolocumab has a favorable benefit-risk profile in PLHIV and effectively reduces LDL-C and non-HDL-C.

	Placebo (DB)/ Evolocumab (OLE) (N=152)	Evolocumab (DB)/ Evolocumab (OLE) (N=299)	All Patients/ Evolocumab (OLE (N=451)
Percent change from baseline in lipid parameters at week 52			
LDL-C, mean (SD), %	-53.70 (21.97)	-59.85 (22.93)	-57.84 (22.77)
Total Cholesterol, mean (SD),%	-33.89 (18.72)	-37.76 (15.78)	-36.50 (16.86)
HDL-C, mean (SD), %	10.07 (19.34)	11.58 (19.56)	11.09 (19.47)
VLDL-C, mean (SD), %	-11.28 (37.97)	-13.85 (33.0)	-13.02 (34.64)
Non-HDL-C, mean (SD), %	-46.72 (22.98)	-51.65 (19.77)	-50.04 (20.97)
Triglycerides, mean (SD), %	-9.64 (41.39)	-13.39 (35.73)	-12.16 (37.65)
Lp(a), mean (SD), %	-13.14 (32.58)	-13.50 (39.56)	-13.38 (37.37)

Baseline is study day 1, prior to administration of double-blind IP. Abbreviation: DB, double-blind; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; Lp(a), lipoprotein(a); Non-HDL-C, non-high-density lipoprotein cholesterol; OLE, open-label extension; SD, standard deviation; VLDL-C, very low-density lipoprotein cholesterol; N, number subjects who received at least one dose of open-label Evolocumab