INTRODUCTION

- Secondary prevention patients already on maximally tolerated lipid lowering therapy (LLT) and not achieving their LDL-C target levels would qualify for apheresis as the last option for further LDL-C lowering.
- The estimated number of patients who are eligible for apheresis in Germany largely exceeds the number of patients currently on apheresis.
- With approximately € 40,000 annual treatment costs per patient, use of apheresis is restricted by having a lengthy and complex approval process.
- According to German authorities, apheresis-treatment is an invasive, burdensome procedure and therefore only applied as “ultima ratio” for high-risk patients with hypercholesterolemia.

OBJECTIVES

Evaluate the potency of evolocumab, an innovative new lipid-lowering agent inhibiting PCSK9, to avoid apheresis treatment in patients who meet the requirements for apheresis eligibility in Germany.

*European marketing authorization has been applied for evolocumab; is still not available on the market.

METHODS

- Individual patient-profiles were derived from the IMS@DA database (2011-2013).
- Efficacy from two evolocumab trials (DESCARTEs2 and LAPLACE-2*) were applied in this model.
- Mean reduction from baseline ranged from 59.3% (95% CI [54.9%, 63.8%]) in DESCARTEs2 to 72.3% (95% CI [69.1%, 75.4%]) in LAPLACE-2**.
- Efficacy was applied to baseline LDL-C levels of the identified patient-profiles using a probabilistic approach.
- The treatment goal in patients with hypercholesterolemia at high risk for CVE is LDL-C <100 mg/dL, according to the German AkAd-guideline.
- Sensitivity-analysis was conducted for LDL-C treatment goal according to ESC guideline with <70 mg/dL.

RESULTS

- 80% of patients in all cohorts (SP, SP + max LLT, SP + max LLT + T2D) were eligible for apheresis at baseline (LDL-C ≥100 mg/dL).
- Applying LAPLACE-2 efficacy regarding predicted LDL-C reduction (Figure 1)
- 100% of patients in all cohorts can possibly avoid apheresis by reaching recommended LDL-C levels < 100 mg/dL.
- 99% in all cohorts reached target according to ESC-guideline (LDL-C levels < 70 mg/dL).
- Applying DESCARTEs efficacy regarding predicted LDL-C reduction (Figure 2)
- 99% of patients in all cohorts can possibly avoid apheresis by reaching recommended LDL-C levels < 100 mg/dL.
- 81%, 84%, and 88% reached target according to ESC-guideline (LDL-C levels < 70 mg/dL) in the SP, the SP + max LLT, and the SP + max LLT + T2D cohort respectively.

DISCLOSURE

This study was sponsored by Amgen GmbH. Villa, Schmid, Lothgren and Michailov are employees of Amgen and thus eligible for stock options.

REFERENCES

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