ODYSSEY ALTERNATIVE: Efficacy and safety of alirocumab versus ezetimibe, in patients with statin intolerance defined by placebo run-in and statin rechallenge arm

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ClinicalTrials.gov identifier: NCT01709513
This study was funded by Sanofi and Regeneron Pharmaceuticals, Inc.
Statin Intolerance (SI): Limits Many Patients from Achieving LDL-C Goals

- SI: Inability to use statins for long-term reduction of lipids and/or CV risk because of significant symptoms and/or biomarker abnormalities that can be temporally attributed to the initiation or dose escalation of statins
- ~10–25% patients in clinical practice report SI
  - Cleveland Clinic
    - Myalgia was most common complaint
    - However, 63.2% patients with previous SI were able to tolerate daily statin therapy

Large, well-controlled randomized trials of cholesterol-lowering drugs in statin intolerant patients are lacking

**ODYSSEY ALTERNATIVE Study Design**

**Statin intolerant patients** (by medical history) with LDL-C \(\geq 70 \text{ mg/dL} \) (very-high CV risk) or \(\geq 100 \text{ mg/dL} \) (moderate/high risk)

**Double-Blind Treatment Period (24 Weeks)**
- **N=100**
  - **Alirocumab 75/150 mg SC Q2W + placebo PO QD**
    - administered via single 1 mL injection using prefilled pen for self-administration
  - Per-protocol dose ↑ possible depending on W8 LDL-C
- **N=100**
  - **Ezetimibe 10 mg PO QD + placebo SC Q2W**
- **N=50**
  - **Atorvastatin 20 mg PO QD + placebo SC Q2W**

Assessments:
- W-4
- W0
- W4
- W8
- W12
- W16
- W24

Patients discontinued if muscle-related AEs reported with placebos during run-in

Per-protocol dose increase if Week 8 LDL-C \(\geq 70 \) or \(\geq 100 \text{ mg/dL} \) (depending on CV risk)

**Primary endpoint**
- LDL-C % change from baseline, ALI and EZE only
- Safety analysis (all groups)

*Unable to tolerate at least two different statins, including one at the lowest dose, due to muscle-related symptoms

\(^{†}\)4-week single-blind placebo run-in follows 2-week washout of statins, ezetimibe and red yeast rice.
OLTP: Alirocumab open-label treatment period; W, Week.
Patient Disposition

Entered placebo run-in (N=361)

Randomized (N=314)

Excluded (N=47)
- 25 due to muscle-related AE during placebo run-in (6.9% of those entering run-in)
- 22 due to other inclusion/exclusion criteria

Alirocumab (N=126) (all patients treated)
- Completed 24 weeks (N=96)
  Discontinued: 23.8% (N=30)
  Due to AE (N=23)
- Primary analysis (N=126)
- Safety analysis (N=126)

Ezetimibe (N=125) (1 patient not treated)
- Completed 24 Weeks (N=82)
  Discontinued: 33.6% (N=42)
  Due to AE (N=31)
- Primary analysis (N=122)
- Safety analysis (N=124)

Atorvastatin (N=63) (all patients treated)
- Completed 24 weeks (N=42)
  Discontinued: 33.3% (N=21)
  Due to AE (N=16)
- Safety analysis only (N=63)
Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Alirocumab (N=126)</th>
<th>Ezetimibe (N=125)</th>
<th>Atorvastatin (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>64.1 (9.0)</td>
<td>62.8 (10.1)</td>
<td>63.4 (8.9)</td>
</tr>
<tr>
<td>Male, %</td>
<td>55.6%</td>
<td>53.6%</td>
<td>55.6%</td>
</tr>
<tr>
<td>Race, white, %</td>
<td>92.9%</td>
<td>92.8%</td>
<td>98.4%</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>29.6 (6.6)</td>
<td>28.4 (4.9)</td>
<td>29.7 (5.4)</td>
</tr>
<tr>
<td>HeFH, %</td>
<td>11.1%</td>
<td>20.0%</td>
<td>12.7%</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>67.5%</td>
<td>61.6%</td>
<td>55.6%</td>
</tr>
<tr>
<td>Type 2 diabetes, %</td>
<td>28.6%</td>
<td>19.2%</td>
<td>23.8%</td>
</tr>
<tr>
<td>CHD history, %</td>
<td>50.8%</td>
<td>43.2%</td>
<td>44.4%</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>8.7%</td>
<td>4.0%</td>
<td>7.9%</td>
</tr>
<tr>
<td>LLT other than statin/ezetimibe</td>
<td>37.3%</td>
<td>44.0%</td>
<td>54.0%</td>
</tr>
</tbody>
</table>

LLT, lipid-lowering therapy
<table>
<thead>
<tr>
<th></th>
<th>Alirocumab (N=126)</th>
<th>Ezetimibe (N=125)</th>
<th>Atorvastatin (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LDL-C (calculated), mg/dL, mean (SD)</strong></td>
<td>191.1 (72.7)</td>
<td>193.5 (70.9)</td>
<td>187.3 (59.5)</td>
</tr>
<tr>
<td><strong>Non-HDL-C, mg/dL, mean (SD)</strong></td>
<td>230.0 (80.4)</td>
<td>229.8 (82.7)</td>
<td>223.8 (64.8)</td>
</tr>
<tr>
<td><strong>Apo B, mg/dL, mean (SD)</strong></td>
<td>141.7 (39.5)</td>
<td>138.2 (37.4)</td>
<td>139.1 (34.7)</td>
</tr>
<tr>
<td><strong>Lp(a), mg/dL, median (IQR)</strong></td>
<td>18 (8:47)</td>
<td>14 (7:43)</td>
<td>12 (6:50)</td>
</tr>
<tr>
<td><strong>Triglycerides, mg/dL, median (IQR)</strong></td>
<td>164 (114:233)</td>
<td>140 (95:218)</td>
<td>158 (119:246)</td>
</tr>
<tr>
<td><strong>HDL-C, mg/dL, mean (SD)</strong></td>
<td>48.9 (15.3)</td>
<td>50.7 (14.1)</td>
<td>51.1 (12.5)</td>
</tr>
<tr>
<td><strong>Apo A1, mg/dL, mean (SD)</strong></td>
<td>149.4 (25.0)</td>
<td>150.0 (24.2)</td>
<td>154.2 (24.8)</td>
</tr>
</tbody>
</table>
Alirocumab Significantly Reduced LDL-C from Baseline to Week 24 versus Ezetimibe

% change from baseline to Week 24 in LDL-C

**ITT (primary endpoint)**
- LS mean difference (SE) vs ezetimibe: -30.4 (3.1); *P*<0.0001
- LS mean difference (SE) vs ezetimibe: -35.1 (2.8); *P*<0.0001
- 49.5%† received 150 mg Q2W at W12
- Absolute change of -33 (4.2) mg/dL

**On-treatment (key secondary endpoint)**
- Absolute change of -84 (4.1) mg/dL
- 49.5%† of 109 patients who received at least one injection after Week 12 had dose increase.

†49.5% of 109 patients who received at least one injection after Week 12 had dose increase.
Alirocumab Maintained LDL-C Reductions Week 4–24

Achieved calculated LDL-C over time – on-treatment analysis (modified ITT – observed data only)

- **Alirocumab**
- **Ezetimibe**

**LDL-C, mean (SE), mg/dL**

- **Alirocumab**
- **Ezetimibe**

- **156 mg/dL**
- **157 mg/dL**

- **Δ 59 mg/dL**
- **Δ 65 mg/dL**

49.5% received 150 mg Q2W at W12
Significantly More SI Patients Achieved Target LDL-C <70 or <100 mg/dL (depending on CV risk) with Alirocumab vs Ezetimibe

Goals: Very high-risk: LDL-C <70 mg/dL, High/moderate-risk: <100 mg/dL

Baseline LDL-C levels (ITT): 191.1 and 194.2 mg/dL in alirocumab and ezetimibe arms.
Baseline LDL-C levels (on-treatment): 188.8 and 195.3 mg/dL in alirocumab and ezetimibe arms.
Significant Reductions in Secondary Lipid Parameters at Week 24

For Lp(a): Adjusted mean (SE) from robust regression with multiple imputation procedure.

LS mean (SE) % change from baseline to Week 24

**ITT On-treatment**

- **Non-HDL-C**
  - Alirocumab: -30% (P<0.0001)
  - Ezetimibe: -28% (P<0.0001)
  - Ezetimibe vs Alirocumab: -2% (P=0.0001)

- **Apo B**
  - Alirocumab: -28% (P<0.0001)
  - Ezetimibe: -26% (P<0.0001)
  - Ezetimibe vs Alirocumab: -2% (P=0.0001)

- **Lp(a)**
  - Alirocumab: -17% (P<0.0001)
  - Ezetimibe: -14% (P<0.0001)
  - Ezetimibe vs Alirocumab: -3% (P=0.0001)

**On-treatment**

- **Non-HDL-C**
  - Alirocumab: -60%
  - Ezetimibe: -50%

- **Apo B**
  - Alirocumab: -46.9%
  - Ezetimibe: -42.6%

- **Lp(a)**
  - Alirocumab: -46.9%
  - Ezetimibe: -42.6%

LS mean difference vs ezetimibe:

- **Non-HDL-C**
  - Alirocumab: -26% (P<0.0001)
  - Ezetimibe: -25% (P<0.0001)

- **Apo B**
  - Alirocumab: -19% (P<0.0001)
  - Ezetimibe: -17% (P=0.0001)

- **Lp(a)**
  - Alirocumab: -19% (P<0.0001)
  - Ezetimibe: -17% (P=0.0001)
## Safety Analysis

### Safety analysis from double-blind treatment period

<table>
<thead>
<tr>
<th></th>
<th>Alirocumab (N=126)</th>
<th>Ezetimibe (N=124)</th>
<th>Atorvastatin (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEAEs†</td>
<td>82.5%</td>
<td>80.6%</td>
<td>85.7%</td>
</tr>
<tr>
<td>Treatment-emergent SAEs</td>
<td>9.5%</td>
<td>8.1%</td>
<td>11.1%</td>
</tr>
<tr>
<td>TEAEs leading to death</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TEAEs leading to discontinuation</td>
<td>18.3%</td>
<td>25.0%</td>
<td>25.4%</td>
</tr>
<tr>
<td>Any skeletal-muscle related TEAE‡</td>
<td>32.5%</td>
<td>41.1%</td>
<td>46.0%</td>
</tr>
<tr>
<td>HR (95% CI) alirocumab vs comparator</td>
<td>-</td>
<td>0.71 (95% CI: 0.47 to 1.06)</td>
<td>0.61 (95% CI: 0.38 to 0.99)</td>
</tr>
<tr>
<td>( P )-value vs alirocumab§</td>
<td>-</td>
<td>0.096</td>
<td>0.042</td>
</tr>
<tr>
<td>Skeletal-muscle related TEAE leading to discontinuation</td>
<td>15.9%</td>
<td>20.2%</td>
<td>22.2%</td>
</tr>
<tr>
<td>HR (95% CI) alirocumab vs comparator</td>
<td>-</td>
<td>0.78 (95% CI: 0.43 to 1.41)</td>
<td>0.67 (95% CI: 0.34 to 1.32)</td>
</tr>
<tr>
<td>( P )-value vs alirocumab§</td>
<td>-</td>
<td>0.409</td>
<td>0.240</td>
</tr>
</tbody>
</table>

†TEAE (treatment emergent adverse event) period = time from first to last injection of study treatment + 70 days.
SAE = serious adverse event.
‡Pre-defined category including myalgia, muscle spasms, muscular weakness, musculoskeletal stiffness, muscle fatigue.
§Although not pre-planned analysis, the \( P \)-value is shown for descriptive purposes.
Fewer Skeletal Muscle AEs with Alirocumab than with Atorvastatin

Kaplan-Meier estimates for time to first skeletal muscle event†

Cox model analysis:
HR ALI vs ATV = 0.61 (95% CI: 0.38 to 0.99), nominal P=0.042
HR ALI vs EZE = 0.71 (95% CI: 0.47 to 1.06), nominal P=0.096

†Pre-defined category including myalgia, muscle spasms, muscular weakness, musculoskeletal stiffness, muscle fatigue.

ALI, alirocumab; ATV, atorvastatin, EZE, ezetimibe.
## Safety Analysis: Additional AEs of Interest

Safety analysis from double-blind treatment period

<table>
<thead>
<tr>
<th>% (n) of patients</th>
<th>Alirocumab (N=126)</th>
<th>Ezetimibe (N=124)</th>
<th>Atorvastatin (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjudicated CV events†</td>
<td>2.4% (n=3)</td>
<td>0.8% (n=1)</td>
<td>1.6% (n=1)</td>
</tr>
<tr>
<td>Ischemia-driven coronary revascularization procedure</td>
<td>2.4% (n=3)</td>
<td>0.8% (n=1)</td>
<td>1.6% (n=1)</td>
</tr>
<tr>
<td>Non-fatal MI</td>
<td>0.8% (n=1)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Injection-site reactions</td>
<td>4.8% (n=6)</td>
<td>4.8% (n=6)</td>
<td>1.6% (n=1)</td>
</tr>
<tr>
<td>Neurocognitive disorders</td>
<td>2.4% (n=3)</td>
<td>1.6% (n=2)</td>
<td>0</td>
</tr>
<tr>
<td>Creatine kinase &gt;3x ULN, % (n/N)</td>
<td>2.4% (3/126)</td>
<td>1.6% (2/123)</td>
<td>4.8% (3/62)</td>
</tr>
<tr>
<td>Myositis*</td>
<td>0</td>
<td>0</td>
<td>1.6% (n=1)</td>
</tr>
<tr>
<td>ALT &gt;3x ULN, % (n/N)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

†Adjudicated CV events categories: CHD death, non-fatal MI, fatal and non-fatal ischemic stroke, unstable angina requiring hospitalization, congestive heart failure requiring hospitalization, ischemia-driven revascularization procedure (PCI, CABG).

*Muscle symptoms with CK ≥3 x ULN and <10 x ULN.

Patients can be reported as having more than one CV event.

ALT, alanine transaminase; ULN, upper limit of normal.
## Safety Analysis: TEAEs Occurring in ≥5% of Patients in Any Group

Safety analysis from double-blind treatment period

<table>
<thead>
<tr>
<th>% (n) of patients</th>
<th>Alirocumab (N=126)</th>
<th>Ezetimibe (N=124)</th>
<th>Atorvastatin (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myalgia</td>
<td>24.6 (31)</td>
<td>23.4 (29)</td>
<td>27.0 (17)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>6.3 (8)</td>
<td>8.1 (10)</td>
<td>3.2 (2)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>5.6 (7)</td>
<td>7.3 (9)</td>
<td>7.9 (5)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5.6 (7)</td>
<td>4.0 (5)</td>
<td>3.2 (2)</td>
</tr>
<tr>
<td>Headache</td>
<td>4.8 (6)</td>
<td>4.8 (6)</td>
<td>6.3 (4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4.8 (6)</td>
<td>3.2 (4)</td>
<td>7.9 (5)</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>4.0 (5)</td>
<td>7.3 (9)</td>
<td>11.1 (7)</td>
</tr>
<tr>
<td>Back pain</td>
<td>4.0 (5)</td>
<td>5.6 (7)</td>
<td>7.9 (5)</td>
</tr>
<tr>
<td>Paraesthesia</td>
<td>3.2 (4)</td>
<td>0</td>
<td>6.3 (4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2.4 (3)</td>
<td>0.8 (1)</td>
<td>6.3 (4)</td>
</tr>
<tr>
<td>Muscular weakness</td>
<td>0.8 (1)</td>
<td>1.6 (2)</td>
<td>6.3 (4)</td>
</tr>
</tbody>
</table>
Patient Disposition – Open Label Treatment Period (OLTP)

Entered placebo run-in (N=361)

Randomized (N=314)

Excluded (N=47)
- 25 due to muscle-related AE during placebo run-in (6.9% of those entering run-in)
- 22 due to other inclusion/exclusion criteria

Alirocumab (N=126)
(all patients treated)
- Completed 24 weeks (N=96)
  Discontinued: 23.8% (N=30)
  Due to AE (N=23)
- Primary analysis (N=126)
- Safety analysis (N=126)
- Entered OLTP (N=117)

Ezetimibe (N=125)
(1 patient not treated)
- Completed 24 Weeks (N=82)
  Discontinued: 33.6% (N=42)
  Due to AE (N=31)
- Primary analysis (N=122)
- Safety analysis (N=124)
- Entered OLTP (N=105)

Atorvastatin (N=63)
(all patients treated)
- Completed 24 weeks (N=42)
  Discontinued: 33.3% (N=21)
  Due to AE (N=16)
- Safety analysis only (N=63)
- Entered OLTP (N=59)

Total in OLTP – all patients receiving alirocumab† (N=281, 89.5%)
Discontinued (N=9), ongoing (N=272)

†Dose ↑ from 75 mg to 150 mg Q2W at W36 based on the LDL-C level at W32 and the judgment of the investigator
## Interim Safety Results from the Ongoing 3-Year OLTP

Safety analysis from start of OLTP up to 52 weeks

- 89.5% of randomized patients entered the OLTP (including 94% of those randomized to atorvastatin).
- All patients in OLTP receive alirocumab 75 mg Q2W (with dose increase possible to 150 mg Q2W after 12 weeks OLTP treatment).

### Table: Safety Analysis

<table>
<thead>
<tr>
<th>Event</th>
<th>Incidence (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) exposure during OLTP (weeks)</td>
<td>13.9 (6.8)</td>
</tr>
<tr>
<td>Any TEAE</td>
<td>55.9% (n=157)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>4.3% (n=12)</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>1.8% (n=5)</td>
</tr>
<tr>
<td>Musculoskeletal stiffness</td>
<td>0.7% (n=2)</td>
</tr>
<tr>
<td>TEAE leading to discontinuation</td>
<td>2.8% (n=8)</td>
</tr>
<tr>
<td>Myalgia (leading to discontinuation)</td>
<td>0.7% (n=2†)</td>
</tr>
</tbody>
</table>

†The two patients who discontinued due to myalgia originally came from the alirocumab and ezetimibe arms, respectively.
## Safety Summary

**ODYSSEY ALTERNATIVE** and alirocumab safety across placebo-controlled studies

<table>
<thead>
<tr>
<th>% of patients</th>
<th>ODYSSEY ALTERNATIVE</th>
<th>Pooled alirocumab Phase 2/3 placebo-controlled studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Double-blind Treatment Period</td>
<td>Open Label Treatment Period</td>
</tr>
<tr>
<td></td>
<td>Alirocumab (N=126)</td>
<td>Ezetimibe (N=124)</td>
</tr>
<tr>
<td>Mean duration of treatment (weeks)</td>
<td>21.5</td>
<td>19.8</td>
</tr>
<tr>
<td>TEAEs†</td>
<td>82.5%</td>
<td>80.6%</td>
</tr>
<tr>
<td>TEAEs leading to discontinuation</td>
<td>18.3%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Any skeletal-muscle related TEAE‡</td>
<td>32.5%</td>
<td>41.1%</td>
</tr>
<tr>
<td>Skeletal-muscle related TEAE leading to discontinuation</td>
<td>15.9%</td>
<td>20.2%</td>
</tr>
</tbody>
</table>

†TEAE period = time from first to last injection of study treatment + 70 days.
‡Pre-defined category including myalgia, muscle spasms, muscular weakness, musculoskeletal stiffness, muscle fatigue.
Conclusions: ODYSSEY ALTERNATIVE

- In a population of statin intolerant patients with very high baseline LDL-C levels (~190 mg/dL):
  - Self-administered alirocumab produced significantly greater LDL-C reductions versus ezetimibe at Week 24 (LS mean difference of 30.4%)
    - Mean achieved LDL-C = 108.5 mg/dL at Week 24
      - 92 mg/dL on-treatment analysis
    - ~50% did not need dose increase to alirocumab 150 mg Q2W at Week 12
    - 42% of alirocumab patients achieved their LDL-C goals at Week 24
  - In this study, alirocumab was better tolerated than atorvastatin (HR ALI vs ATV = 0.61 (95% CI: 0.38 to 0.99), nominal P=0.042)
    - Fewer patients with skeletal muscle-related TEAEs (myalgia, muscle spasms, muscular weakness, musculoskeletal stiffness, and muscle fatigue) with alirocumab than with atorvastatin and ezetimibe
  - Fewer skeletal muscle events observed to date in the alirocumab OLTP compared with the main study
    - Only two of 281 patients discontinued due to myalgia
Overview of the ODYSSEY Phase 3 Program

Fourteen global Phase 3 trials including >23 500 patients across >2000 study centres

<table>
<thead>
<tr>
<th>HeFH population</th>
<th>HC in high CV-risk population</th>
<th>Additional populations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Add-on to max tolerated statin (± other LLT)</strong></td>
<td><strong>Add-on to max tolerated statin (± other LLT)</strong></td>
<td><strong>Add-on to max tolerated statin (± other LLT)</strong></td>
</tr>
<tr>
<td>ODYSSEY FH I (NCT01623115; EFC12492) LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=486; 18 months</td>
<td>ODYSSEY COMBO I (NCT01644175; EFC11568) LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=316; 12 months</td>
<td>ODYSSEY MONO (NCT01644474; EFC11716) Patients on no background LLTs LDL-C $\geq$100 mg/dL n=103; 6 months</td>
</tr>
<tr>
<td>ODYSSEY FH II (NCT01709500; CL1112) LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=249; 18 months</td>
<td>†ODYSSEY COMBO II (NCT01644188; EFC11569) LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=720; 24 months</td>
<td>ODYSSEY ALTERNATIVE (NCT01709513; CL1119) Patients with defined statin intolerance LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=314; 6 months</td>
</tr>
<tr>
<td>ODYSSEY HIGH FH (NCT01617655; EFC12732) LDL-C $\geq$160 mg/dL n=107; 18 months</td>
<td></td>
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</tr>
<tr>
<td>ODYSSEY OLE (NCT01954394; LTS 13463) Open-label study for FH from EFC 12492, CL 1112, EFC 12732 or LTS 11717 n=1000; 30 months</td>
<td></td>
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</tr>
<tr>
<td>ODYSSEY LONG TERM (NCT01507831; LTS11717) LDL-C $\geq$70 mg/dL n=2341; 18 months</td>
<td>ODYSSEY OUTCOMES (NCT01663402; EFC11570) LDL-C $\geq$70 mg/dL n=18 000; 64 months</td>
<td>ODYSSEY OPTIONS I (NCT01730040; CL1110) Patients not at goal on moderate-dose atorvastatin LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=355; 6 months</td>
</tr>
<tr>
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<td></td>
<td>ODYSSEY OPTIONS II (NCT01730053; CL1118) Patients not at goal on moderate-dose rosuvastatin LDL-C $\geq$70 mg/dL OR LDL-C $\geq$100 mg/dL n=305; 6 months</td>
</tr>
</tbody>
</table>

†For ODYSSEY COMBO II other LLT not allowed at entry.
Thank You to All Principal Investigators and National Coordinators!

67 sites worldwide

- Canada: 3 sites
- USA: 40 sites
- Austria: 3 sites
- Italy: 3 sites
- Norway: 2 sites
- UK: 5 sites
- France: 6 sites
- Israel: 5 sites

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