Results of ODYSSEY OUTCOMES Trial

Evaluation of long-term cardiovascular outcomes after Acute Coronary Syndrome (ACS) during treatment with Praluent® (alirocumab)

Investor call at ACC, Orlando, March 10, 2018
Sanofi Forward-Looking Statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development of new products, including future clinical trial results and analysis of clinical data (including post-marketing data), decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates. There are additional risks that may cause actual results to differ materially from those contemplated by the forward-looking statements, such as the lack of commercial success of certain product candidates once approved, pricing pressures, both in the United States and abroad, including pharmaceutical reimbursement and pricing, the future approval and commercial success of therapeutic alternatives, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, changes in applicable laws or regulations, the impact of cost containment initiatives and subsequent changes thereto, as well as those risks and uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.
Regeneron Forward-Looking Statements

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Agenda

Opening remarks
- Olivier Brandicourt, MD - Chief Executive Officer, Sanofi
- Leonard S. Schleifer, MD, PhD - Founder, President and Chief Executive Officer, Regeneron

Detailed Review of ODYSSEY OUTCOMES data
- Dr Eric Peterson, MD, MPH, FAHA, FACC - Distinguished Professor of Medicine in the Division of Cardiology and Executive Director of the Duke Clinical Research Institute

Praluent® Value Proposition
- Jay Edelberg, MD, PhD - Vice President, Global Cardiovascular Development, Sanofi
- Marion McCourt - Senior Vice President and Head of Commercial, Regeneron

Concluding remarks
- Olivier Brandicourt, MD - Chief Executive Officer, Sanofi
- Leonard S. Schleifer, MD, PhD - Founder, President and Chief Executive Officer, Regeneron

Q&A Session
Opening Remarks

- Olivier Brandicourt, MD - Chief Executive Officer, Sanofi
- Leonard S. Schleifer, MD, PhD - Founder, President and Chief Executive Officer, Regeneron
Patients with a History of ACS and High LDL-C Represent a High Risk Population in CVD, A Major Global Unmet Need

- Cardiovascular disease kills more people worldwide than any other disease
- Patients with acute coronary syndrome (ACS), such as heart attack, are at high risk despite statin therapy
  - Heart attack is a common ACS event associated with an increased mortality risk
- Following ACS, the risk for future cardiovascular events (residual risk), including death, is high and related to levels of low-density lipoprotein-cholesterol (LDL-C)

CVD = Cardiovascular Disease; LDL-C = low-density lipoprotein cholesterol

(1) World Health Organization (2017)
(2) Benjamin EJ et al. Circulation. 2017;135:e146-e603
(3) World Heart Foundation.
The Majority of Patients Do Not Achieve LDL-C Targets on Statin Therapy

- Due to a variety of reasons, at least 50% of patients discontinue statins within 1 year of treatment initiation\(^1\)
- Statin intolerance occurs in up to 15% of patients\(^2\)

**Patient Population on Statin Therapy**

- Patients with ASCVD
- Patients with HeFH

**Patients that remained >100 mg/dL**

- 29%\(^3\)
- 98%\(^3\)

ASCVD = Atherosclerotic Cardiovascular Disease; CV = cardiovascular; HeFH = heterozygous familial hypercholesterolemia

ODYSSSEY OUTCOMES is the first non-statin, lipid-lowering study to be associated with a reduction of all-cause mortality (1).

**Discovery of the LDL-C Receptor**
- Drs. Brown and Goldstein discover the LDL-C receptor
- First statin (simvastatin) study to show an all-cause mortality benefit (primary endpoint)
- Study demonstrated a 30% reduction in all-cause mortality
- Enrolled patients with baseline LDL-C of 186 mg/dL. On treatment lowering of 65 mg/dL
- Sponsored by Merck & Co, under the leadership of Dr. Roy Vagelos (Chairman of REGN Board)
- Changed paradigm of treating CV disease with statins

**1974**

**1988-1994**

**2003–Today**

**4S Study was First to Show that a Statin Could Reduce Both CV and All-Cause Mortality in High-Risk Patients**

**PCSK9 From Discovery to Clinic**
- 2003: PCSK9 (NARC-1) characterized (2)
- 2006: PCSK9 LOF mutations associated with 28% ↓ LDL-C (3)
- 2010: First subject treated with (alirocumab) PCSK9 inhibitor (4)
- 2015: FDA approves Praluent, the first PCSK9 inhibitor (5)

**2003:**
- PCSK9 (NARC-1) characterized
- PCSK9 LOF mutations associated with 28% ↓ LDL-C
- First subject treated with (alirocumab) PCSK9 inhibitor
- FDA approves Praluent, the first PCSK9 inhibitor

**The use of Praluent® to reduce the risk of major adverse CV events is investigational and has not been evaluated by any regulatory authority.**

**CHD=Coronary Heart disease; LDL=Low-Density Lipoprotein; LDL-C=Low-Density Lipoprotein Cholesterol; LOF=Loss Of Function; mAb=monoclonal antibody; PCSK9=Proprotein Convertase Subtilisin/Kexin type 9.**

(1) HR=0.85; CI: 0.73-0.98; nominal p value = 0.026
(5) PRALUENT Prescribing Information. Sanofi/Regeneron Pharmaceuticals, 2015

The use of Praluent® to reduce the risk of major adverse CV events is investigational and has not been evaluated by any regulatory authority.
Detailed Review of ODYSSEY OUTCOMES Data

- Dr Eric Peterson, MD, MPH, FAHA, FACC - Distinguished Professor of Medicine in the Division of Cardiology and Executive Director of the Duke Clinical Research Institute
Treatment Assignment

Post-ACS patients (1 to 12 months)

Run-in period of 2–16 weeks on high-intensity or maximum-tolerated dose of atorvastatin or rosuvastatin

At least one lipid entry criterion met

Randomization

Alirocumab SC Q2W

Placebo SC Q2W

Patient and investigators remained blinded to treatment and lipid levels for the entire duration of the study

Patient Disposition

Randomized 18,924 patients

- **Alirocumab (N=9462)**
  - Follow-up*: median 2.8 (Q1–Q3 2.3–3.4) years
  - 8242 (44%) patients with potential follow-up ≥3 years
  - 1955 patients experienced a primary endpoint
  - 726 patients died

- **Placebo (N=9462)**
  - Follow-up*: median 2.8 (Q1–Q3 2.3–3.4) years
  - 8242 (44%) patients with potential follow-up ≥3 years
  - 1955 patients experienced a primary endpoint
  - 726 patients died

- **Premature treatment discontinuation**
  - Alirocumab: 1343 (14.2%)
  - Placebo: 1496 (15.8%)

- **Blinded switch to placebo**
  - (2 consecutive LDL-C values <15 mg/dL)
  - Alirocumab: 730 (7.7%)
  - Placebo: Not applicable

- **Patients lost to follow-up (vital status)**
  - Alirocumab: 14
  - Placebo: 9

*Ascertainment was complete for 99.1% and 99.8% of potential patient-years of follow-up for the primary endpoint and all-cause death, respectively
LDL-C: ITT and On-Treatment Analyses

*Excludes LDL-C values after premature treatment discontinuation or blinded switch to placebo
†All LDL-C values, including those after premature treatment discontinuation, blinded down titration, or blinded switch to placebo
Primary Efficacy Endpoint: MACE

MACE: CHD death, non-fatal MI, ischemic stroke, or unstable angina requiring hospitalization

ARR* 1.6%

HR 0.85
(95% CI 0.78, 0.93)
P=0.0003

*Based on cumulative incidence
# Primary Efficacy and Components

<table>
<thead>
<tr>
<th>Endpoint, n (%)</th>
<th>Alirocumab (N=9462)</th>
<th>Placebo (N=9462)</th>
<th>HR (95% CI)</th>
<th>Log-rank P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>903 (9.5)</td>
<td>1052 (11.1)</td>
<td>0.85 (0.78, 0.93)</td>
<td>0.0003</td>
</tr>
<tr>
<td>CHD death</td>
<td>205 (2.2)</td>
<td>222 (2.3)</td>
<td>0.92 (0.76, 1.11)</td>
<td>0.38</td>
</tr>
<tr>
<td>Non-fatal MI</td>
<td>626 (6.6)</td>
<td>722 (7.6)</td>
<td>0.86 (0.77, 0.96)</td>
<td>0.006</td>
</tr>
<tr>
<td>Ischemic stroke</td>
<td>111 (1.2)</td>
<td>152 (1.6)</td>
<td>0.73 (0.57, 0.93)</td>
<td>0.01</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>37 (0.4)</td>
<td>60 (0.6)</td>
<td>0.61 (0.41, 0.92)</td>
<td>0.02</td>
</tr>
</tbody>
</table>
**All-Cause Death**

![Graph showing All-Cause Death over time for Placebo and Alirocumab groups. The graph indicates that Alirocumab has a lower All-Cause Death rate compared to Placebo, with a hazard ratio (HR) of 0.85 (95% CI 0.73, 0.98) and a p-value of 0.026.](image)

- **ARR† 0.6%**
- **HR 0.85**
  (95% CI 0.73, 0.98)
- **P=0.026***

*Nominal P-value
†Based on cumulative incidence
Post Hoc Analysis: All-Cause Death by Baseline LDL-C Subgroups

ARR* 1.7%  \( P_{\text{interaction}} = 0.12 \)

- <80 mg/dL
  - HR 0.89
  - (95% CI 0.69, 1.14)

- 80 to <100 mg/dL
  - HR 1.03
  - (95% CI 0.78, 1.36)

- ≥100 mg/dL
  - HR 0.71
  - (95% CI 0.56, 0.90)

*Based on cumulative incidence
Efficacy: Subgroup with Baseline LDL-C ≥100 mg/dL (Median Baseline LDL-C 118 mg/dL)

<table>
<thead>
<tr>
<th>Endpoint, n (%)</th>
<th>Alirocumab (N=2814)</th>
<th>Placebo (N=2815)</th>
<th>Absolute risk reduction (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>324 (11.5)</td>
<td>420 (14.9)</td>
<td>3.4</td>
<td>0.76 (0.65, 0.87)</td>
</tr>
<tr>
<td>CHD death</td>
<td>69 (2.5)</td>
<td>96 (3.4)</td>
<td>1.0</td>
<td>0.72 (0.53, 0.98)</td>
</tr>
<tr>
<td>CV death</td>
<td>81 (2.9)</td>
<td>117 (4.2)</td>
<td>1.3</td>
<td>0.69 (0.52, 0.92)</td>
</tr>
<tr>
<td>All-cause death</td>
<td>114 (4.1)</td>
<td>161 (5.7)</td>
<td>1.7</td>
<td>0.71 (0.56, 0.90)</td>
</tr>
</tbody>
</table>
## Safety (1)

<table>
<thead>
<tr>
<th>Treatment-emergent adverse events, n (%)</th>
<th>Alirocumab (N=9451)</th>
<th>Placebo (N=9443)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>7165 (75.8)</td>
<td>7282 (77.1)</td>
</tr>
<tr>
<td>Serious</td>
<td>2202 (23.3)</td>
<td>2350 (24.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratory value</th>
<th>Alirocumab</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT &gt;3 × ULN, n/N (%)</td>
<td>212/9369 (2.3)</td>
<td>228/9341 (2.4)</td>
</tr>
<tr>
<td>Creatine kinase &gt;10 × ULN, n/N (%)</td>
<td>46/9369 (0.5)</td>
<td>48/9338 (0.5)</td>
</tr>
</tbody>
</table>
### Safety (2)

<table>
<thead>
<tr>
<th>Event</th>
<th>Alirocumab (N=9451)</th>
<th>Placebo (N=9443)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes worsening or diabetic complications: <em>pts w/DM at baseline, n/N (%)</em></td>
<td>506/2688 (18.8)</td>
<td>583/2747 (21.2)</td>
</tr>
<tr>
<td>New onset diabetes; *pts w/o DM at baseline, n/N (%)</td>
<td>648/6763 (9.6)</td>
<td>676/6696 (10.1)</td>
</tr>
<tr>
<td>General allergic reaction, n (%)</td>
<td>748 (7.9)</td>
<td>736 (7.8)</td>
</tr>
<tr>
<td>Hepatic disorder, n (%)</td>
<td>500 (5.3)</td>
<td>534 (5.7)</td>
</tr>
<tr>
<td>Local injection site reaction, n (%)*</td>
<td>360 (3.8)</td>
<td>203 (2.1)</td>
</tr>
<tr>
<td>Neurocognitive disorder, n (%)</td>
<td>143 (1.5)</td>
<td>167 (1.8)</td>
</tr>
<tr>
<td>Cataracts, n (%)</td>
<td>120 (1.3)</td>
<td>134 (1.4)</td>
</tr>
<tr>
<td>Hemorrhagic stroke, n (%)</td>
<td>9 (&lt;0.1)</td>
<td>16 (0.2)</td>
</tr>
</tbody>
</table>

*HR vs. placebo 1.82 (95% CI 1.54, 2.17)
Conclusions

Compared with placebo in patients with recent ACS, alirocumab 75 or 150 mg subcutaneous Q2W targeting LDL-C levels 25–50 mg/dL, and allowing levels as low as 15 mg/dL:

1. Reduced MACE, MI, and ischemic stroke
2. Was associated with a lower rate of all-cause death
3. Was safe and well-tolerated over the duration of the trial
Clinical Perspective

• In this nearly 19,000-patient placebo-controlled trial, including many patients treated for ≥3 years, there was no safety signal with alirocumab other than injection site reactions
Clinical Perspective

• In this nearly 19,000-patient placebo-controlled trial, including many patients treated for ≥3 years, there was no safety signal with alirocumab other than injection site reactions.

• Among patients with ACS and baseline LDL-C ≥100 mg/dL, alirocumab reduced MACE by 24% (ARR 3.4%) and all-cause death by 29% (ARR 1.7%) compared with placebo.
  ➢ These are the patients who may benefit most from treatment.

ARR, absolute risk reduction
Praluent® Value Proposition

- Jay Edelberg, MD, PhD - Vice President, Global Cardiovascular Development, Sanofi
- Marion McCourt - Senior Vice President and Head of Commercial, Regeneron
# ODYSSEY Phase 3 Program - Consistent Positive Results

22 global trials, including more than 29,300 patients across more than 3,000 study centers

<table>
<thead>
<tr>
<th>HeFH population</th>
<th>HC in high CV risk population</th>
<th>Additional populations/studies</th>
</tr>
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<tbody>
<tr>
<td>Add-on to max tolerated statin (± other LMT)</td>
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<td></td>
</tr>
</tbody>
</table>

**ODYSSEY OUTCOMES (EFC11570) N=18,600**
- LDL-C ≥ 70 mg/dL
- Event-driven, 2 year minimum follow-up
- Conducted in 57 countries
- Enrollment Completed November 2015

**ODYSSEY COMBO I (EFC11568) N=316**
- LDL-C ≥ 70 mg/dL OR LDL-C ≥ 100 mg/dL
- 12 months

**ODYSSEY COMBO II (EFC11569) N=720**
- LDL-C ≥ 70 mg/dL
- 24 months

**ODYSSEY EAST (EFC13389) N=600**
- LDL-C ≥ 70 mg/dL OR LDL-C ≥ 100 mg/dL
- 6 months

**ODYSSEY KT (EFC14074) N=199**
- LDL-C ≥ 70 mg/dL OR ≥ 100 mg/dL
- 6 months

**ODYSSEY DM – Insulin (LPS14355) N=500**
- LDL-C ≥ 70 mg/dL
- 6 months

**ODYSSEY DM – Dyslipidemia (LPS14354) N=420**
- Non-HDL-C ≥ 100 mg/dL
- 6 months

**ODYSSEY OLE (LTS13463) N=1000**
- Patients with HeFH from one of four parent studies
- 30 months

**ODYSSEY FH I (EFC12492) N=486**
- LDL-C ≥ 70 mg/dL OR LDL-C ≥ 100 mg/dL
- 18 months

**ODYSSEY FH II (CL1112) N=249**
- LDL-C ≥ 70 mg/dL OR LDL-C ≥ 100 mg/dL
- 18 months

**ODYSSEY HIGH FH (EFC12732) N=107**
- LDL-C ≥ 160 mg/dL
- 18 months

**ODYSSEY LONG TERM (LTS11717) N=2,341**
- LDL-C ≥ 70 mg/dL
- 18 months

**ODYSSEY JAPAN (EFC13672) N=216**
- LDL-C ≥ 100 mg/dL OR LDL-C ≥ 120 mg/dL
- 12 months

**ODYSSEY APPRISE (LPS14245) N=1300**
- LDL-C ≥ 100 mg/dL OR LDL-C ≥ 120 mg/dL
- 3 – 30 months

**ODYSSEY ESCAPE (R727-CL1216) N=63**
- Patients undergoing LDL-apheresis therapy
- 4 months

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**ODYSSEY COMBO II**
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- 6 months

**ODYSSEY DM – Insulin**
- LDL-C ≥ 70 mg/dL
- 6 months

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**ODYSSEY ESCAPE**
- Patients undergoing LDL-apheresis therapy
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**Primary endpoint met; data presented or published**
ODYSSSEY OUTCOMES Provides Strong Clinical Evidence of Patient Benefit from Long-Term Therapy with Praluent®

**Transformational Study**
- High risk patients with ACS event between 1 and 12 months
- Patient follow-up for up to 5 years with >40% of patients followed up for more than 3 years
- >90% of patients enrolled in the study were on maximally tolerated statin therapy

**Positive Results**
- Primary endpoint met: Significant reduction in MACE
- Reduction in all-cause mortality (2)
- No new safety signals in the trial: Well tolerated in the longest PCSK9 inhibitor trial

**Patient Impact**
- Greatest clinical benefit demonstrated in high risk post-ACS patients
- In highest risk patients with LDL-C ≥100mg/dL, Praluent was associated with a 28% reduction in the risk of CHD death, 31% reduction in CHD death, and 29% reduction in all-cause death

MACE=Major Adverse Cardiac Event; CV=Cardiovascular; CHD=Cardiac Heart Disease

(1) In addition to maximally tolerated statin therapy

(2) HR= 0.85; CI 0.73-0.98; nominal p value = 0.0261
Sanofi and Regeneron Committed to Make Praluent® Accessible for Patients with Greatest Health Risk and Unmet Need

- Precision medicine approach will focus efforts on high-risk patients, such as those who have had heart attacks or unstable angina and cannot reduce their LDL-C below 100 mg/dL despite maximally-tolerated statins

- For payers willing to reduce access barriers for high-risk patients, companies will offer net price within a cost-effective range, leveraging a new ICER analysis

Sanofi and Regeneron will engage with payers to offer a cost-effective net price to those who agree to provide straightforward access for patients with greatest need
Concluding remarks

- Olivier Brandicourt, MD - Chief Executive Officer, Sanofi
- Leonard S. Schleifer, MD, PhD - Founder, President and Chief Executive Officer, Regeneron
Building the Opportunity for Praluent® Based on Strong Body of Clinical Data from ODYSSEY Study Program

- Engage with healthcare providers to address high risk patient population
- Increase access for appropriate patients by working together with payers
- Submission to regulators for label inclusion of ODYSSEY program data
- Potential update of treatment guidelines based on ODYSSEY OUTCOMES
ODYSSEY OUTCOMES Establishes the Platform to Optimize the Long-Term Benefits of Praluent® Treatment for Patients

- Met primary endpoint with 15% RRR of major CV events / MACE
- The first non-statin, lipid-lowering trial to be associated with a reduction in all-cause mortality (nominal p=0.026)
- For patients with LDL-C $\geq 100$ mg/dL, all MACE endpoints were meaningfully improved
- Consistent benefit was observed across individual endpoints
- With up to 5 years double-blind follow-up period, no imbalance observed in overall safety and safety of interest between groups
Q&A Session

- Olivier Brandicourt, MD - Chief Executive Officer, Sanofi
- Leonard S. Schleifer, MD, PhD - Founder, President and Chief Executive Officer, Regeneron
- Dr Eric Peterson, MD, MPH, FAHA, FACC - Distinguished Professor of Medicine in the Division of Cardiology and Executive Director of the Duke Clinical Research Institute
- Jay Edelberg, MD, PhD - Vice President, Global Cardiovascular Development, Sanofi
- Marion McCourt - Senior Vice President and Head of Commercial, Regeneron