News Releases

Praluent® (alirocumab) significantly reduced risk of cardiovascular events in high-risk patients, and was associated with lower death rate

- ODYSSEY OUTCOMES trial met its primary endpoint, demonstrating that high-risk patients who added Praluent® (alirocumab) to maximally-tolerated statins experienced significantly fewer major adverse cardiovascular events compared to those on maximally-tolerated statins alone
- For the first time, adding a lipid-lowering therapy to maximally-tolerated statins was associated with reduced death from any cause
- More pronounced effect observed in patients with baseline LDL-C levels at or above despite maximally-tolerated statins, who are at high risk of suffering a future event; in this group, Praluent reduced risk of major adverse cardiovascular events by 24% and was associated with a 29% lower risk of death overall
- In this 18,924-patient, long-term trial, the safety profile of Praluent was consistent with previous trials and no new safety issues were observed

LAVAL, QC, March 10, 2018 /CNW Telbec/ - Sanofi and Regeneron Pharmaceuticals, Inc. today announced that the ODYSSEY OUTCOMES trial met its primary endpoint, showing Praluent® (alirocumab) significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who had suffered a recent acute coronary syndrome (ACS) event such as a heart attack. Results from the trial was presented today during a late-breaker session at the American College of Cardiology's 67th Annual Scientific Session (ACC.18) in Orlando, Florida and are available here.

Key findings include:

- On the primary endpoint, Praluent reduced the overall risk of MACE by 15% (HR=0.85, CI: 0.78-0.93, p=0.0003). The MACE composite endpoint includes patients who experienced a heart attack, ischemic stroke, death from coronary heart disease (CHD), or unstable angina requiring hospitalization.
- Praluent was also associated with a lower risk of death overall, known as "all-cause mortality" (HR=0.85; CI: 0.73-0.98, nominal p=0.026), and there were also numerically fewer CHD deaths (HR=0.92; CI: 0.76-1.11, p=0.38).
- In a pre-specified analysis, the patients with baseline LDL-C levels at or above 100 mg/dL (2.6 mmol/L) experienced a more pronounced effect from Praluent, reducing their risk of MACE by 24% (HR=0.76, CI: 0.65-0.87). In a post-hoc analysis of this group, Praluent was associated with a lower risk of death from any cause by 29% (HR=0.71, CI: 0.56-0.90).
- The analyses described above include the results from 730 patients (8%) in the Praluent group who continued to be assessed in the Praluent arm despite stopping active Praluent therapy, as specified in the protocol for patients with persistent LDL-C readings below 15 mg/dL.
- For those in the Praluent treatment arm, approximately 75% of patient time was on the 75 mg dose.
- There were no new safety signals in the trial, with injection site reactions experienced more commonly in the Praluent group compared to patients on maximally-tolerated statins alone (3.8% Praluent; 2.1% placebo). There was no difference in neurocognitive events (1.5% Praluent; 1.8% placebo) or new-onset diabetes (9.6% Praluent; 10.1% placebo).

"This trial was consistent with earlier statin trials, showing the greatest benefit in patients with higher cholesterol levels at baseline," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer, Regeneron. "Many patients who have survived a recent heart attack or other coronary event are unable to reach an LDL cholesterol goal of less than 100 mg/dL, and have an urgent need for new therapeutic options because of their increased risk of another event. In this trial, such patients who received Praluent on top of maximally-tolerated statins had important reductions in their risk."

"Not all patients with heart disease are the same. Through this trial, we have been able to identify high-risk patients treated with optimal statins who still have an urgent need for additional treatment options," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "With nearly 90 percent of the patients in this trial on high-intensity statins, the data demonstrate that a precision-medicine approach in the field of cardiovascular disease may further advance how we better treat high-risk patients."

"The results of this study, the only one specifically designed to evaluate the long-term clinical benefit of Praluent initiation with patients post acute coronary syndrome, demonstrate the value that Praluent can bring to the health of those who are unable to reach their LDL-C health goals," claimed Niven Al-Khoury, President, Sanofi Canada. "With over 60 years of experience working to understand and support the healthcare needs of patients, bringing valuable solutions is core to our purpose."

About ODYSSEY OUTCOMES

ODYSSEY OUTCOMES (n=18,924) assessed the effect of Praluent on the occurrence of MACE in patients who had experienced an ACS between 1-12 months (median 2.6 months) before enrolling in the trial, and who were already on maximally-tolerated statins. All patients were randomized to receive Praluent (n=9,462) or a placebo (n=9,462) and were treated for an average (median) of 2.8 years, with some patients being treated for up to five years. Approximately 90% of patients were on a high-intensity statin.

The trial was designed to maintain patients' LDL-C levels between 25-50 mg/dL (0.6 -1.3 mmol/L), using two different doses of Praluent (75 mg and 150 mg). Praluent-treated patients started the trial on 75 mg every 2 weeks, and switched to 150 mg every 2 weeks if their LDL-C levels remained above 50 mg/dL (1.3 mmol/L) (n=2,615). Some patients who switched to 150 mg switched back to 75 mg if their LDL-C fell below 25 mg/dL (0.6 mmol/L) (n=805), and patients who experienced two consecutive LDL-C measurements below 15 mg/dL (0.4 mmol/L) while on the 75 mg dose (n=730) stopped active Praluent therapy for the remainder of the trial.

About Praluent
Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells, which lowers LDL-C levels in the blood. The use of Praluent to reduce the risk of MACE is investigational and has not been evaluated by any regulatory agency.

Praluent is approved in more than 60 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as the European Union (EU).

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

For the product monograph: http://products.sanofi.ca/en/praluent.pdf

About Regeneron Pharmaceuticals, Inc
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led by physician-scientists for 30 years, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite®* technologies, including *VelocImmune®* to yield optimized fully-human antibodies, and ambitious initiatives such as the Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About Sanofi
Sanofi (EURONEXT: SAN) (NYSE: SNY) is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi entities in Canada employ close to 1,900 people. In 2016 we invested $130 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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