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Primary efficacy endpoints met in all nine new trials of investigational PCSK9 inhibitor
Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that nine new Phase 3 ODYSSEY trials of alirocumab in people with hypercholesterolemia met their primary efficacy endpoint of a greater percent reduction from baseline in low-density lipoprotein cholesterol (LDL-C) at 24 weeks compared to placebo or active comparator. Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).
In the nine ODYSSEY trials, the mean percent reduction in LDL-C from baseline at 24 weeks in alirocumab-treated patients was consistent with results seen in previous alirocumab trials. The nine trials included ODYSSEY LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II and ALTERNATIVE. All patients received alirocumab in addition to standard-of-care lipid-lowering therapy, with the exception of some patients in ODYSSEY ALTERNATIVE.
The 2,341-patient ongoing ODYSSEY LONG TERM trial evaluated the long-term safety and efficacy of alirocumab compared to placebo. Both treatment groups received statins and some patients also received additional lipid-lowering therapies. The trial met its primary efficacy endpoint at 24 weeks. A pre-specified interim safety analysis was performed when all patients reached one year and approximately 25 percent of patients reached 18 months of treatment. A lower rate of adjudicated major cardiovascular events (cardiac death, myocardial infarction, stroke, and unstable angina requiring hospitalization) was observed in the alirocumab arm compared to placebo in a post-hoc analysis (p-value of less than 0.05). The potential of alirocumab to demonstrate cardiovascular benefit is being prospectively assessed in an ongoing 18, 000-patient ODYSSEY OUTCOMES trial.
Alirocumab was generally well tolerated in the 9 ODYSSEY trials.
The most common adverse events were nasopharyngitis and upper respiratory tract infections, which were generally balanced between treatment groups. Injection site reactions occurred more often in the alirocumab group compared to placebo. Serious adverse events and deaths were generally balanced between treatment groups as were other key adverse events including musculoskeletal, neurocognitive and liver-related events.
"Clinical data to date show consistent, positive results in LDL-C lowering, with an encouraging safety and tolerability profile across all Phase 3 alirocumab trials that we have reported," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President, Regeneron Laboratories. "Importantly, in the trials that used an individualized approach with 75 mg and 150 mg doses, the majority of patients reached their LDL-C goal while remaining on a 75 mg dose. This dosing approach was designed to provide physicians and patients with the flexibility to tailor therapy to patients' lipid-lowering needs."
The ODYSSEY ALTERNATIVE trial evaluated patients with a history of intolerance to two or more statins, who were randomized to receive alirocumab, ezetimibe or atorvastatin 20 mg (a calibrator arm). This trial met its primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks with alirocumab compared to ezetimibe. In the ALTERNATIVE trial, rates of discontinuation due to adverse events were 25 percent for atorvastatin, 25 percent for ezetimibe and 18 percent for alirocumab; these differences between treatment groups were not statistically significant.
"The robust data from these studies in more than 5,000 patients is the basis of our global regulatory submissions, which we expect in the U.S. and EU by year end," said Elias Zerhouni, M.D., President, Global R
D, Sanofi. "We look forward to potentially providing a new treatment option for patients who may need a more aggressive cholesterol-lowering treatment on top of standard of care."
More detailed data will be presented at upcoming medical congresses.
The ODYSSEY trials assessed the potential of subcutaneous alirocumab in one or more patient groups where there is high unmet need:
- Heterozygous Familial hypercholesterolemia (HeFH), an inherited form of high cholesterol: ODYSSEY FH I, FH II and HIGH FH focused solely on patients in this group. HeFH is an inherited disorder of lipid metabolism that predisposes a person to high LDL-C and premature severe cardiovascular disease (CVD).1
- High or very high cardiovascular (CV) risk: ODYSSEY COMBO I, COMBO II, OPTIONS I, OPTIONS II and LONG TERM.
- Patients with a history of statin-intolerance: ODYSSEY ALTERNATIVE included patients who had a history of being intolerant to statins and at moderate- to very-high CV risk.
The 9 ODYSSEY trials reported today, along with the previously announced MONO trial, encompass over 5,000 patients studied in double-blind trials for 24-104 weeks. ODYSSEY MONO reported positive results in October 2013. All trials included patients with LDL-C not at goal with or without a documented history of CVD. ODYSSEY OPTIONS I, OPTIONS II, COMBO II, MONO and ALTERNATIVE included at least one active comparator (e.g., ezetimibe). The trials evaluated two distinct dosing regimens: 150 milligrams (mg) every two weeks or 75 mg every two weeks increasing to 150 mg if needed to reach protocol-specified LDL-C targets. The 75 mg and the 150 mg dose were delivered with a single, self-administered one-milliliter (mL) injection.
The ODYSSEY clinical trial program remains ongoing. This includes three additional studies, CHOICE I, CHOICE II (both evaluating monthly doses of alirocumab) and OUTCOMES, which are expected to report primary endpoints in 2015 and beyond. Click here for more information on the ODYSSEY program, alirocumab, PCSK9, and LDL-C. Alirocumab is currently under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority.
About Sanofi
Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).
About Regeneron Pharmaceuticals, Inc.
Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York, that discovers, invents, develops, manufactures, and commercializes biologic medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com .
Sanofi Forward-Looking Statements
This press release 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, future clinical data and analysis, including post marketing, 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, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those 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, 2013. 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
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and

uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation alirocumab; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials, such as the ODYSSEY global trial program; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation alirocumab; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2013 and its Form 10-Q for the quarter ended March 31, 2014. The reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.
References:
1.Reiner Z, Catapano AL, De Backer G, et al [on behalf of the Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS)]. ESC/EAS Guidelines for the management of dyslipidaemias. European Heart Journal 2011;32:1769-1818. Available at: http://www.escardio.org/guidelines-surveys/esc-guidelines/guidelinesdocuments/guidelines-dyslipidemias-ft.pdf .

Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
65926 Frankfurt am Main
Telefon: 069/305-5085
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Pressekontakt

Sanofi-Aventis

65926 Frankfurt am Main

Firmenkontakt

Sanofi-Aventis

65926 Frankfurt am Main

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