Sanofi and Regeneron Report Positive Top-line Results with Alirocumab from First Phase 3 Study of a PCSK9 Inhibitor for LDL Cholesterol Reduction

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alirocumab monotherapy reduced "bad cholesterol three times more than ezetimibe
Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the Phase 3 ODYSSEY MONO trial with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), met its primary efficacy endpoint. The mean low-density lipoprotein-cholesterol (LDL-C, or "bad cholesterol) reduction from baseline to week 24, the primary efficacy endpoint of the study, was significantly greater in patients randomized to alirocumab, as compared to patients randomized to ezetimibe (47.2% vs. 15.6%, p<0.0001). In the trial, which employed a dose increase (up-titration) for patients who did not achieve an LDL-C level of 70 milligrams/deciliter (mg/dL), the majority of patients remained on the initial low dose of alirocumab of 75 milligrams (mg).
"We are excited with the findings from the first Phase 3 trial with alirocumab. While the majority of our clinical program is investigating alirocumab in combination with lipid-lowering therapies, these monotherapy results are encouraging, said Jay Edelberg M.D., Ph.D., Head of the PCSK9 Development and Launch Unit, Sanofi Group. "As in this trial, several of our Phase 3 studies will utilize an up-titration approach, the aim of which is to bring patients to goal with the lowest effective dose of anti-PCSK9 antibody. We look forward to results from the remaining Phase 3 trials, which are investigating alirocumab in a variety of patient populations, combinations with different background therapies, and dosing regimens.
The percentage of patients who reported treatment emergent adverse events was 78.4% in the ezetimibe group and 69.2% in the alirocumab group. The most common class of adverse events was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related adverse events occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab.
ODYSSEY MONO is the first study to report data from the 12 Phase 3 trials that have been initiated so far as part of the more than 23,000 patient ODYSSEY clinical trial program.
"There are still millions of people around the globe who have poorly controlled LDL-C, said George D. Yancopoulos, M.D., Ph. D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "Three years ago, our Phase 1 trials generated the first clinical evidence that blocking PCSK9 could markedly lower cholesterol levels in humans. Today, it is very gratifying to be able to report the first Phase 3 data for this promising potential new class of lipid-lowering agents. It is important to point out that these are just the first of a large amount of data yet to come from our extensive ODYSSEY Phase 3 program.
ODYSSEY MONO (N=103) was a randomized, double-blind, active-controlled, parallel-group study to evaluate the efficacy and safety of alirocumab over 24 weeks in patients with primary hypercholesterolemia and moderate cardiovascular risk. Patients in the trial were randomized to receive monotherapy with either ezetimibe 10 mg, an alternative to statin therapy, or alirocumab. Alirocumab was self-administered initially at its low dose of 75 mg every two weeks, and was up-titrated at week 12 to 150 mg if the LDL-C measurement at week 8 was above 70 mg/dL. The majority of alirocumab patients in the trial remained on the initial low dose of alirocumab because they achieved LDL-C below 70 mg/dL at week 8. Alirocumab was self-administered subcutaneously using a single-use 1 milliliter (mL) auto-injector.
Detailed results from the ODYSSEY MONO study will be presented at an upcoming medical conference in 2014.
About ODYSSEY
The global Phase 3 ODYSSEY program is expected to enroll more than 23,000 patients and currently includes 12 clinical trials of alirocumab both in combination with other lipid-lowering agents and as monotherapy. The primary Phase 3 study endpoint is the percent mean reduction in LDL-C at 24 weeks, giving a robust measure of efficacy and safety. In addition, several other lipid markers will also be assessed.
The ODYSSEY
Phase 3 trials are designed to create different options to help meet the needs of individual patients. In addition to the up-titration option explored in this study in which patients received a 75 mg Q2W (once every two weeks) dose of alirocumab, and were only be up-titrated to 150 mg Q2W if they were unable to reach prespecified target LDL-C levels, the other ODYSSEY trials are also exploring initiating patients with a 150 mg every two week regimen (intended for patients needing a larger reduction in LDL-C), as well as regimens evaluating alirocumab dosed once every four weeks.
All of the ODYSSEY trials, with the exception of ODYSSEY CHOICE I and ODYSSEY OUTCOMES, are fully enrolled. For more information on the ODYSSEY clinical trials, please visit http://www.odysseytrials.com .
About PCSK9
PCSK9 is known to be a determinant of circulating LDL levels, as it binds to LDL receptors resulting in their degradation so that fewer are available on liver cells to remove excess LDL-cholesterol from the blood. Moreover, traditional LDL-lowering therapies such as statins actually stimulate the production of PCSK9, which limits their own ability to lower LDL-cholesterol. Blocking the PCSK9 pathway is therefore a potentially novel mechanism for lowering LDL-cholesterol.
About alirocumab
Alirocumab is an investigational, fully-human monoclonal antibody that targets and blocks PCSK9. It is administered via subcutaneous injection. By inhibiting PCSK9, a determinant of circulating LDL-C levels in the blood, alirocumab has been shown in pre-clinical studies to increase the number of LDL receptors on hepatocytes, thereby lowering LDL-C.
The investigational agent described above 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 medicines for the treatment of serious medical conditions. Regeneron markets 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, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com .

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