New Cholesterol Treatment Now Available for Canadians

As 8 in 10 Canadian GPs identify the need for new cholesterol treatment options, Canadian Patients now have access to PRALUENT™

Montreal, Quebec, May 24, 2016 - Sanofi Canada is pleased to announce that PRALUENT (alirocumab), solution for subcutaneous injection, is now available in Canada for the treatment of bad cholesterol, known as low-density lipoprotein cholesterol (LDL-C), in certain adult patients. PRALUENT is indicated as an adjunct to diet and maximally-tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of LDL-C. The effect of PRALUENT on cardiovascular morbidity and mortality has not been determined.

PRALUENT belongs to a new class of cholesterol medication known as PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitors[i] , and was jointly developed by Sanofi and Regeneron Pharmaceuticals.

The arrival of PRALUENT could help address the current gaps in cholesterol treatment and offer an important new option in the management of this disease to patients. High cholesterol is one of the major risk factors for coronary heart disease and stroke[ii], and despite available treatment, including statins, many Canadian patients face an ongoing challenge of achieving their target LDL-C levels. In fact, **approximately 40% of Canadians live with high cholesterol**[iii] and **45% of them do not meet their target LDL-C levels**[iv].

Moreover, according to a 2015 Leger survey* of active Canadian general practitioners, fewer than half (46%) of GPs agree that all of their patients receive the optimal level of care with statins, and almost 8 in 10 (78%) agree that **there is a need for additional cholesterol treatments** that would work in conjunction with statins.

“The Canadian healthcare provider community is encouraged by the arrival of PRALUENT, given the extensive clinical trial evidence of its ability to dramatically lower LDL – considered bad – cholesterol when used in conjunction with established cholesterol lowering therapies such as statins,” said Dr. Shaun Goodman, Staff Cardiologist and Associate Head in the Division of Cardiology, Department of Medicine, at St. Michael’s Hospital in Toronto. “The PCSK9 inhibitor class of cholesterol lowering treatment is also characterized by its remarkable safety profile. We anticipate that PCSK9 inhibitors such as PRALUENT will have a significant impact on many Canadian patients living with elevated cholesterol and who cannot currently achieve their cholesterol goals with diet and lifestyle modifications as well as the use of statins.”

“Sanofi is tremendously proud to build upon its heritage in cardiovascular therapies to help lead the way towards a new, highly effective and safe form of cholesterol treatment for millions of Canadians,” said Niven Al-Khoury, General Manager, Diabetes and Cardiovascular Care, at Sanofi Canada. “The arrival of PRALUENT allows Sanofi to offer a new solution to Canadians struggling to manage their high cholesterol, in particular those living with genetic conditions such as heterozygous familial hypercholesterolemia and patients with high arteriosclerotic risk of cardiovascular disease, who are not achieving the optimal benefit from their current cholesterol therapies.”

PRALUENT is available to Canadian patients in two doses (75 mg and 150 mg). Both are offered in a single 1 milliliter (mL) injection delivered in a single-dose prefilled pen or syringe that patients can self-administer every two weeks.

About PRALUENT

Alirocumab works by blocking the action of PCSK9, a naturally occurring protein that prevents the liver from clearing LDL cholesterol out of the blood,[v,vi,vii] thereby allowing the liver to clear more LDL cholesterol from the blood, and so reduces LDL cholesterol levels[i].

The approval of PRALUENT was based on data from the pivotal Phase 3 ODYSSEY program, which included current standard of care therapy (statins) and showed consistent, positive results for PRALUENT when compared to placebo and ezetimibe in reducing LDL-cholesterol. ODYSSEY LONG TERM trial was an 18-months study that evaluated PRALUENT 150 mg every two weeks versus placebo when added to current standard of care, including maximally tolerated statins. ODYSSEY COMBO II trial was a two-year trial that compared PRALUENT with ezetimibe, both added to current standard of care including maximally tolerated statins. Patients received a 75 mg dose of PRALUENT every two weeks, with a dose up-titration to 150 mg at week 12 based on pre-specified criteria. A proportion of 81.6% of patients remained on their initial dose of 75 mg.

PRALUENT is generally well-tolerated with an acceptable safety profile. Local injection site reactions, including erythema/redness, itching, swelling, or pain/tenderness, where the injection is given were common events (7.2 percent with PRALUENT vs. 5.1 percent with placebo) and resulted in a low discontinuation rate that was comparable to placebo (0.2 percent with PRALUENT vs. 0.4 percent with placebo). Other common adverse events occurring more frequently in patients taking PRALUENT versus placebo included symptoms of the common cold and flu or flu-like symptoms.

ODYSSEY Program

The ODYSSEY Phase 3 program is one of the most comprehensive clinical trial programs ever conducted for an investigational LDL cholesterol lowering therapy. The program includes 14 global Phase 3 trials evaluating more than 23,500 patients, including Canadian participants. The primary efficacy end point in all of the studies was the mean percent reduction from baseline in LDL cholesterol at week 24 compared to control; all of the completed studies met their primary endpoint. A significantly higher proportion of patients achieved a LDL-C of less than 1.8mmol/L in the PRALUENT group as compared to control. The ongoing ODYSSEY OUTCOMES trial is prospectively evaluating the cardiovascular benefits of PRALUENT in approximately 18,000 patients.

** The Leger study was conducted with an online panel of 50 general practitioners/family doctors across Canada between August 6 and 15, 2015.*

About Sanofi – www.sanofi.ca

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi entities in Canada include the Diabetes and Cardiovascular Diseases Business Unit, the General Medicines, Established Products and Consumer Healthcare Business Unit, Sanofi Pasteur (vaccines), Sanofi Genzyme (rare diseases, multiple sclerosis and oncology) and Merial (animal health). Together

they employ close to 1,700 people. In 2015 Sanofi companies invested $133.5 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) 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 commercializes medicines for eye diseases, 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, atopic dermatitis and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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