KYYNAMRO™ (mipomersen sodium) Data Presented at XVI International Symposium on Atherosclerosis

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Phase 3 Extension Study Highlights Long-term Safety and Efficacy in Patients with Familial Hypercholesterolemia (FH)

CAMBRIDGE, Mass. & CARLSBAD, Calif.--(BUSINESS WIRE)--Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), and Isis Pharmaceuticals Inc. (NASDAQ: ISIS), announced today that new two-year data from a phase 3 long-term extension study of KYYNAMRO™ (mipomersen sodium) were presented at the XVI International Symposium on Atherosclerosis in Sydney, Australia. In the study, patients treated with KYYNAMRO™ for two years maintained robust reductions in LDL-C and all other Apo B containing atherogenic lipoproteins measured with a safety profile consistent with the phase 3 studies of KYYNAMRO™.

Data presented today included 141 patients who enrolled in the study after having completed one of the three phase 3 studies: homozygous FH, severe hypercholesterolemia, or the heterozygous FH. These studies were six months long and required patients to be on stable maximally tolerated lipid-lowering therapy throughout the study. To date, 63 patients remain on or have completed treatment with 40 patients consenting to participate for another two years of treatment - a total of four years of treatment.

In this study, sustained reductions in LDL-C with a mean reduction of 28 percent in LDL-C at six months and at two years were observed in patients treated with KYYNAMRO™. Changes in liver fat were observed in some patients where the overall median change stabilized and then declined with continued treatment. The median change from baseline in percent liver fat increased from 5 percent at 26 weeks, to 13 percent at 52 weeks, and returned to 5 percent at 104 weeks. Results represent those patients in the extension study at each assessment period: 60 patients at 26 weeks, 31 patients at 52 weeks, and 39 patients at 104 weeks. The median change reflects both patients who continued at full dose as well as those with dose adjustments and dose interruptions. Upon treatment discontinuation, changes in liver fat returned towards normal.

“These data show that robust LDL-C reductions are seen in patients treated for 2 years and more. Liver fat may increase in some patients but in this long term study the median fat fraction is seen to stabilize and decline with time as measured by MRI,” said study investigator Raul D. Santos, M.D., Ph.D., Director of the Lipid Clinic of the Heart Institute, Instituto do Coração, Hospital das Clínicas, São Paulo, Brazil. “These results are encouraging and support the potential for effective and safe long-term use in patients with the most aggressive forms of FH.”

Genzyme and Isis have completed the four phase 3 studies that are included in the European submission and will be included in the U.S. submission. In these studies, the most commonly observed adverse events were injection site reactions and flu-like symptoms. The long-term data demonstrate a safety and efficacy profile consistent with phase 3 findings.

“These positive and clinically meaningful results represent a significant addition to the KYYNAMRO™ clinical development program,” said Vice President and General Manager of Genzyme’s Cardiovascular Business, Paula Soteropoulos. “We look forward to continuing to work with regulatory authorities to bring this treatment to market for such a severe and life-threatening disease.”

KYYNAMRO™ is the registered trade name submitted to health authorities for investigational agent mipomersen. Genzyme submitted for EU marketing approval of KYYNAMRO™ for the treatment of patients with homozygous FH (HoFH) and severe heterozygous FH (Severe HeFH) in July 2011. Genzyme also expects to submit an NDA for U.S. approval for the HoFH indication by the end of March 2012.

Webcast

At 4:00 p.m. Eastern Time today, Isis will host a live conference call webcast and slide presentation with Dr. Raul D. Santos to discuss KYYNAMRO™ data presented at the International Symposium on Atherosclerosis. Interested parties may listen to the call by dialing 866.761.0749 and refer to the passcode “ISIS 2012” or access the webcast with or without audio at www.isispharm.com. A webcast replay will be available for a limited time at the same address.

About KYYNAMRO™ (mipomersen sodium)

KYYNAMRO™ is a first-in-class Apo B synthesis inhibitor currently in late-stage development for patients with homozygous familial hypercholesterolemia (HoFH) and severe heterozygous familial hypercholesterolemia (Severe HeFH) to further reduce
LDL cholesterol (LDL-C) in patients already maintaining a stable regimen of maximally tolerated lipid-lowering therapies. It is intended to reduce LDL-C by preventing the formation of atherogenic lipoproteins, the particles that carry cholesterol through the bloodstream. KYNAMRO™ acts by blocking the production of, apolipoprotein B (Apo B), the protein that provides the structural core for these atherogenic particles, including LDL and lipoprotein-a (Lp(a)).

About Familial Hypercholesterolemia (FH)

FH is a genetic disease that results in elevated LDL-C levels and family patterns of increased risk of premature heart disease and heart disease-related death. FH patients have inherited abnormalities in liver cells that are responsible for clearing LDL particles from the blood. FH is autosomal dominant, which means that all first-degree relatives of FH patients have a 50 percent chance of having the disease as well, making early detection through family screening critically important.

The most severe FH patients have LDL-C levels that are two to four times higher than recommended levels, even when taking multiple cholesterol-lowering medications. These people, who are characterized as having severe FH, include: those who have inherited the disease from both parents (HoFH) and those who have inherited it from only one parent, and have a particularly severe form of the disease (Severe HeFH) defined as those people who are maximally treated and still have LDL-C greater than 200 mg/dL (5.1 mmol) with coronary heart disease or greater than 300 mg/dL (7.1 mmol) without coronary heart disease. People with HoFH may have aggressive heart disease beginning in childhood, and even with today's therapies remain at significant risk of cardiovascular events. Learn more at www.FHJourneys.com.

About Genzyme, a Sanofi Company

Genzyme has pioneered the development and delivery of transformative therapies for patients affected by rare and debilitating diseases for over 30 years. We accomplish our goals through world-class research and with the compassion and commitment of our employees. With a focus on rare diseases and multiple sclerosis, we are dedicated to making a positive impact on the lives of the patients and families we serve. That goal guides and inspires us every day. Genzyme's portfolio of transformative therapies, which are marketed in countries around the world, represents groundbreaking and life-saving advances in medicine. As a Sanofi company, Genzyme benefits from the reach and resources of one of the world's largest pharmaceutical companies, with a shared commitment to improving the lives of patients. Learn more at www.genzyme.com.

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About Sanofi

Sanofi, a global and diversified 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 Isis Pharmaceuticals, Inc.

Isis is exploiting its leadership position in antisense technology to discover and develop novel drugs for its product pipeline and for its partners. Isis' broad pipeline consists of 25 drugs to treat a wide variety of diseases with an emphasis on cardiovascular, metabolic and severe and rare/neurodegenerative diseases, and cancer. Isis' partner, Genzyme, plans to commercialize Isis' lead product, KYNAMRO, following regulatory approval, which is expected in 2012. Isis' patents provide strong and extensive protection for its drugs and technology. Additional information about Isis is available at www.isispharm.com.

Isis Pharmaceuticals® is a registered trademark of Isis Pharmaceuticals, Inc.

Sanofi Forward Looking Statement

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, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Isis Forward Looking Statement

This press release includes forward-looking statements regarding Isis' collaboration with Genzyme Corporation, its financial and business development activities, and the development, activity, therapeutic and commercial potential and safety of
KYNAMRO in treating patients with high cholesterol. Any statement describing Isis’ goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. Isis’ forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Isis’ forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Isis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Isis’ programs are described in additional detail in Isis’ annual report on Form 10-K for the year ended December 31, 2011, which is on file with the SEC. Copies of this and other documents are available from the Company.

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English

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