Genzyme and Isis Announce Filing of U.S. NDA for KYNAMRO™ (mipomersen sodium) in Homozygous Familial Hypercholesterolemia

May 29, 2012

Isis earns $25 million milestone payment

CAMBRIDGE, Mass. & CARLSBAD, Calif.--(BUSINESS WIRE)--

Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), and Isis Pharmaceuticals Inc. (ISIS), announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for KYNAMRO ™ (mipomersen sodium) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH). The NDA filing with the FDA triggers a $25 million milestone payment to Isis from Genzyme.

"The NDA filing with the FDA represents a significant achievement in the development of KYNAMRO ™ and our efforts to get this important new drug to the market for patients who are at high-risk of a cardiovascular event," said David Meeker, M.D., President and CEO, Genzyme. "We look forward to continuing the review process with the U.S. and EU regulatory authorities to bring KYNAMRO ™ to patients in need."

Genzyme submitted an application for U.S. marketing approval of KYNAMRO ™ for the treatment of patients with HoFH in March 2012. The application will be subject to a standard review and will have a Prescription Drug User Fee Act (PDUFA) date of January 29, 2013. In July 2011, Genzyme submitted an application for EU marketing approval of KYNAMRO™ for the treatment of patients with HoFH and severe heterozygous FH (Severe HeFH).

"We believe that KYNAMRO ™ has the potential to bring real benefit to patients in the United States with HoFH who are unable to adequately control their LDL-C with currently available treatments," said B. Lynne Parshall, Chief Operating Officer and CFO of Isis. "The successes of our joint development efforts for KYNAMRO ™ are evident in the significant progress made in bringing this important new drug to the regulatory agencies for review. We are pleased to have earned the first regulatory milestone payment for KYNAMRO ™ from this collaboration."

The FDA submission for KYNAMRO ™ is supported by the largest clinical trial conducted to date in the HoFH patient population. In the randomized, double-blind, placebo controlled, multi-center trial, significant reductions were observed in all atherogenic lipoproteins evaluated (including LDL-C, Apo B and Lp(a)) for patients receiving KYNAMRO ™ who are already receiving a regimen of maximally tolerated lipid lowering therapies including statins. Three patients (12 percent) treated with KYNAMRO ™ withdrew due to adverse events. Consistent with other studies evaluating KYNAMRO ™, commonly observed adverse events included mild to moderate injection site reactions and flu-like symptoms, as well as elevations in liver transaminases.

KYNAMRO™ is the registered trade name submitted to health authorities for investigational agent mipomersen.

About KYNAMRO™ (mipomersen sodium)

KYNAMRO™ 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, and who require additional, significant lipid lowering therapy. 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.

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 (BSAC) and in New York (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 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, 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, a Sanofi company, and the development, activity, therapeutic benefit and safety of KYNAMRO™ in treating patients with high cholesterolAny statement describing Isis' goals, expectations, financial or other projections, intentions or beliefs, including the planned commercialization of KYNAMRO, 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 and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from the Company.

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