New Study Findings Confirm CLEXANE®/LOVENOX® Long-Term Clinical Benefit In Patients Suffering From Acute Coronary Syndrome

Paris, France, September 2, 2007 – Sanofi-aventis announced today that one year findings from the landmark ExTRACT-TIMI 25 and STEEPLE studies confirm clear net clinical benefit for patients with acute ST-segment elevation myocardial infarction (STEMI) for Lovenox® vs Unfractionnated Heparin (UFH). The ExTRACT-TIMI 25 and STEEPLE one year results were presented during hotline sessions at the European Society of Cardiology (ESC) Congress in Vienna, Austria.

ExTRACT–TIMI 25 (Enoxaparin and Thrombolysis Reperfusion for Acute Myocardial Infarction Treatment, Thrombolysis in Myocardial Infarction -- Study 25) trial showed that in patients with STEMI treated with fibrinolysis, at one year, the primary endpoint of death or nonfatal myocardial infarction remained significantly in favor of enoxaparin vs UFH (15.8% vs 17.0% p=0.01). Net clinical benefit (all cause of death / nonfatal MI / nonfatal disabling stroke) was also significantly in favour of enoxaparin vs UFH through one year of follow up (16.0% vs 17.3% p=0.007).

“This was a very large trial with conclusive results at 30 days. The persistence of significant net clinical benefit a full year after treatment is further evidence of the viability of the strategy of using enoxaparin as adjunctive anticoagulant therapy to fibrinolysis in the STEMI patient population,” noted ExTRACT TIMI 25 principal investigator Dr. Elliott Antman, M.D., Senior Investigator TIMI Study Group, Director, Samuel A. Levine Cardiac Unit at Brigham and Women’s Hospital, Professor of Medicine, Harvard Medical School, and lead investigator of the ExTRACT-TIMI 25 study.

ExTRACT TIMI 25 was a major randomized clinical trial that supported the worldwide submission and subsequent approval by the FDA and some European countries of the new Lovenox® indication for the treatment of patients with acute ST-segment elevation myocardial infarction (STEMI).

STEEPLE (SafeTy and Efficacy of Enoxaparin in Percutaneous Coronary Intervention Patients) trial one year follow up shows that the composite of all cause death at 1 year and major bleeding was 3.1% for Lovenox® 0.5 mg/kg (p=0.06 vs. UFH), 3.4% for Lovenox® 0.75 mg/kg (p=0.07 vs. UFH), 3.3% for the two Lovenox® arms combined (p=0.03 vs. UFH) and 4.7% for UFH.

There were low and statistically similar 1-year death rates in the enoxaparin groups (0.5mg/kg or 0.75 mg/kg) and UFH during and after elective percutaneous intervention (PCI). In addition to patient risk factors, ischemic events and major bleeding were found to be independent predictors of death at 1 year.

Commenting on the results, Dr. Gilles Montalescot who is Professor of Cardiology at the Institute of Cardiology, Hôpital de la Pitié Salpêtrière, Institut du Coeur, Paris, France and a member of the STEEPLE steering committee noted, “The significant reduction in major bleeding and similar efficacy compared with UFH confirms Lovenox® is an appropriate anticoagulant for elective PCI.”
About Coronary Artery Disease (CAD) and Acute Coronary Syndrome (ACS)

Coronary artery disease (CAD) is the most common type of heart disease globally and is a serious health problem worldwide. CAD causes approximately 17 million deaths per year: the equivalent of one out of every three deaths worldwide. According to the American Heart Association, more than 13 million Americans have a history of CAD and 7.5 million have experienced an acute heart attack.

Acute coronary syndrome (ACS) is an umbrella term used to describe a group of clinical diagnoses caused by narrowing of the coronary arteries and cover any group of clinical symptoms compatible with acute myocardial ischemia, caused by an imbalance between myocardial oxygen supply and demand that results from CAD.

Immediate treatment is required for all ACS. The treatment approach is multifaceted and aims to try and protect the affected heart muscle from further damage, reinstate blood flow through the artery and reduce the heart’s demand for oxygen. In the emergency room, the primary goals are to rapidly identify patients with MI (STEMI), exclude alternative causes of chest pain, and stratify patients into low- and high-risk groups and provide appropriate therapy to minimize further damage or ischemia to cardiac muscle.

Restoration of blood to the heart (reperfusion) can be achieved either via the use of certain drugs (fibrinolytics), used to break down blood clots, or mechanically by surgery, i.e. Percutaneous Coronary Intervention (PCI). Pharmacological options for the treatment ACS include the use of antiplatelet agents, to help prevent platelets from sticking together and forming clots, and anticoagulants to prevent blood clotting. Anticoagulants prevent clots from growing and new ones from forming, but they do not dissolve clots.

About Percutaneous Coronary Intervention (PCI)

PCI is a treatment procedure that unblocks coronary arteries that have narrowed due to atherosclerosis or atherothrombosis. The procedure restores coronary arterial flow (or coronary perfusion) in an acutely or sub-acutely occluded artery during acute myocardial infarction or unstable angina. PCI includes balloon angioplasty and implantation of intracoronary stent. The main long-term concern of PCI is re-stenosis. However, the use of coated and drug-eluting stents has been shown to reduce this risk. Primary PCI is defined as intervention in the culprit vessel within 12 hours after the onset of chest pain or other symptoms of acute myocardial infarction, without prior (full or concomitant) thrombolytic or other clot-dissolving therapy. Elective PCI is performed in all other less-urgent cases in patients with coronary artery disease (CAD).

About Clexane® / Lovenox® (enoxaparin)

Lovenox® is a unique chemical entity in a class of antithrombotic agents known as low-molecular weight heparin (LMWH). The no. 1 selling low-molecular weight heparin in the world, Lovenox® is obtained by alkaline degradation of heparin benzyl ester and is about one-third the molecular size of unfractionated heparin. Lovenox® is the most widely studied LMWH, with 20 years of use in the treatment of 185 million patients in 96 countries. Its clinical applications are linked to its antithrombotic properties. It is used to inhibit clot formation in venous and arterial vessels to prevent potential acute or chronic complications of venous or arterial thrombosis. As with all anticoagulants, the most frequently reported side effect with Lovenox® is bleeding. Clinical indications for Lovenox® may vary from one country to another.
About sanofi-aventis
Sanofi-aventis is one of the world’s leading pharmaceutical companies, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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 financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis’ 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-aventis, 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 those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

References:
