FDA approves Lovenox® (Enoxaparin Sodium Injection) for the most severe type of heart attack

- Lovenox® is a Low-Molecular Weight Heparin, approved in the United States for the broadest range of indications -

Paris, France, May 18, 2007 – Sanofi-aventis announced today that the Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for the anticoagulant Lovenox® (enoxaparin sodium injection) for the treatment of patients with acute ST-segment elevation myocardial infarction (STEMI). Lovenox® has been shown to reduce the rate of the combined endpoint of recurrent myocardial infarction or death in patients with acute STEMI receiving thrombolysis and being managed medically or with Percutaneous Coronary Intervention (PCI).

STEMI is a severe type of heart attack in which an artery is generally completely blocked by blood clot for sufficient time causing heart muscle damage.

The FDA approval is based on the results of the landmark ExTRACT-TIMI 25 trial (Enoxaparin and Thrombolysis Reperfusion for Acute Myocardial Infarction Treatment, Thrombolysis In Myocardial Infarction - 25 Study), which included more than 20,000 acute STEMI patients and the results of which were published in the April 6, 2006 edition of the New England Journal of Medicine.

The ExTRACT-TIMI 25 study showed that in patients with STEMI treated with fibrinolysis, enoxaparin significantly reduced the rate of death or recurrent infarction at 30 days by 17% vs. unfractionated heparin (UFH) (9.9% vs. 12.0% p<0.001). This benefit of enoxaparin, as compared to UFH, was observed both in patients who underwent percutaneous coronary intervention within 30 days after randomization or who where treated medically. The rates of major bleeding (including intracranial hemorrhage) at 30 days were 2.1% in the enoxaparin group and 1.4% in the UFH group (p<0.001). The 30 day rate of the composite endpoint of death, myocardial nonfatal re-infarction or nonfatal intracranial hemorrhage (a measure of net clinical benefit) was significantly lower in the enoxaparin group as compared to the unfractionated heparin group (10.1% vs. 12.2%, p<0.001).

“The FDA approval is a significant milestone in the evaluation of treatment options of patients with STEMI,” said 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. “With its new indication, enoxaparin is now applicable across the full spectrum of acute coronary syndrome conditions including unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) and ST-segment elevation myocardial infarction (STEMI).”

Sanofi-aventis has also submitted a dossier for the STEMI indication in European countries including France, Germany, UK, Italy and Spain.
About Coronary Artery Disease and Acute Coronary Syndrome

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 Lovenox®

Lovenox® is an antithrombotic agent known as low-molecular weight heparin (LMWH). The number one 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 15 years of use in the treatment of 130 million patients in 96 countries.

Lovenox® is approved in the United States for the prophylaxis of ischemic complications of unstable angina and non-Q-wave (non-ST-segment elevation) myocardial infarction when concurrently administered with aspirin and for the prophylaxis of deep vein thrombosis (DVT) which may lead to pulmonary embolism (PE); in patients undergoing abdominal surgery who are at risk for thromboembolic complications; in patients undergoing hip replacement surgery (during and following hospitalization), in patients undergoing knee replacement surgery; and in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness; as well as for the inpatient treatment of acute DVT, with or without PE, when administered in conjunction with warfarin sodium and for the outpatient treatment of acute DVT without PE, when administered in conjunction with warfarin sodium.
About Deep Vein Thrombosis and Pulmonary Embolism

Deep vein thrombosis (DVT) entails the formation of blood clots within deep veins of the body, most commonly occurring in the lower extremity. DVT occurs in up to two million individuals in the United States each year. Pulmonary embolism (PE), a serious complication of DVT, at times fatal, is responsible for the death of approximately 300,000 people each year in the United States -- more than breast cancer and AIDS combined.

The main problem underneath DVT involves a blockage of blood flow within the deep veins involved, owing to the formation of a blood clot within. Symptoms of acute leg pain and swelling may occur, as consequence of the blockade to blood flow. A PE occurs when part of the blood clot dislodges from its nest in the deep veins, and travels up stream by way of the blood flow, eventually reaching the lung, where it remains trapped. There are many symptoms associated with PE, but the most common ones include shortness of breath, lateral chest pain worsened by deep breath in. There are well known risk factors to DVT, including prolonged immobility, major surgery, chronic medical ailments, cancer, age above 40 years, trauma, oral contraceptives, pregnancy and the post-partum.

The management of DVT includes prophylaxis, under certain risk conditions, and acute treatment in patients with a known DVT. The management of DVT involves several treatments including early mobilization, anti-embolism stockings or mechanical, leg-compression devices to enhance blood flow, and anticoagulants and/or blood-thinning drugs. It is important to consult your healthcare professional about the signs and symptoms associated with DVT.

About sanofi-aventis

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, 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.