



## **FDA Grants Priority Review to Lovenox<sup>®</sup> (Enoxaparin Sodium Injection) Supplemental New Drug Application (sNDA) for acute heart attack**

- Filing for STEMI Indication Also Submitted in Europe -

**Bridgewater, NJ, February 7, 2007** – Sanofi-aventis announced today the Food and Drug Administration (FDA) has accepted for review a supplemental new drug application (sNDA) for the anticoagulant Lovenox<sup>®</sup> (enoxaparin sodium injection) for the treatment of patients with acute ST-segment elevation myocardial infarction (STEMI), a type of acute heart attack. STEMI is a heart attack in which an artery is generally completely blocked for sufficient time to cause heart muscle damage. This blockage is caused by blood clot formation in the heart arteries.

The FDA has designated the filing for priority review, which is granted to applications in which a new indication or new drug product, if approved, would present a significant improvement compared to currently available therapies or marketed products. The company has also submitted a filing in European countries including France, Germany, UK, Italy and Spain.

Lovenox is a low-molecular weight heparin (LMWH) approved in 96 countries with seven indications (which may vary from one country to another) for the prophylaxis and treatment of thromboembolic disease, including prophylaxis of ischemic complications of unstable angina and non-Q-wave (non-ST-segment elevation) myocardial infarction and the prophylaxis of deep-vein thrombosis (DVT), a condition that may lead to pulmonary embolism (PE).

The FDA filing is based on the results of the landmark ExTRACT-TIMI 25 trial (Enoxaparin and Thrombosis Reperfusion for Acute Myocardial InfarCtion Treatment, Thrombolysis In Myocardial Infarction – Study 25), which was published in the April 2006 edition of the *New England Journal of Medicine* and presented at the 2006 American College of Cardiology's 55<sup>th</sup> Annual Scientific Session. The study included more than 20,000 acute STEMI patients who were eligible to receive fibrinolytic therapy.

### **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.

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.

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 Venous Thromboembolism (VTE)**

Venous thromboembolism is a general term used to describe the formation of a blood clot (thrombus) that block a vessel which main common manifestations are deep-vein thrombosis (DVT) and pulmonary embolism (PE)

#### **About DVT and PE**

DVT is a condition resulting from the formation of a blood clot inside a deep vein, commonly located in the calf or thigh. DVT occurs when the blood clot either partially or completely blocks the flow of blood in the vein. A PE is a potentially life-threatening complication and occurs when a fragment of a blood clot breaks loose and travels to the lungs. Symptoms of a PE may include shortness of breath, rapid pulse, excessive sweating, sharp chest pain and very low blood pressure.

DVT can strike almost anyone at risk. Factors and conditions that may increase the risk of DVT include: immobility, injury, obesity, smoking, oral contraceptives, pregnancy, surgery and/or illnesses including cancer.

Treatments for DVT include early mobilization, sequential compression devices to prevent blood clotting, and anticoagulants and/or blood-thinning drugs

#### **About Lovenox® (Enoxaparin)**

Enoxaparin is an anticoagulant of the low molecular weight heparin (LMWH) class. Its clinical applications are linked to its antithrombotic properties. It is used to inhibit clot formation in venous or arterial vessels to avoid potential acute or chronic complications of venous or arterial thrombosis such as pulmonary embolism, myocardial infarction or death of cardiovascular origin. As with all anticoagulants, the most frequently reported side effect for enoxaparin is bleeding. Lovenox is the most widely studied LMWH, with 15 years of use in the treatment of 130 million patients in 96 countries.



### **About sanofi-aventis**

Sanofi-aventis is one of the world's leading pharmaceutical companies. Backed by a world-class R&D organization, 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. 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 and expectations with respect to future operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expect," "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, 2004. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

Contact: Amy Ba, 908 981-6563, [Amy.Ba@sanofi-aventis.com](mailto:Amy.Ba@sanofi-aventis.com)  
Marisol Peron, 908 981-6565, [Marisol.Peron@sanofi-aventis.com](mailto:Marisol.Peron@sanofi-aventis.com)

###