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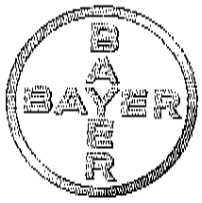

Investor News

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Bayer and Global Regulatory Authorities Evaluating Published Reports on Trasylol

Bayer will publish and mail letters to Health Care Professionals

Leverkusen / February 8, 2006 – Bayer HealthCare is working with global regulatory authorities to evaluate recent reports published in the medical literature concerning Trasylol® (aprotinin injection) and communicating guidance to physicians and the public concerning these reports. These articles report an association of aprotinin/Trasylol with an increased risk of cardiovascular events[1] (myocardial infarction or heart failure), cerebrovascular events[1] such as stroke, encephalopathy or coma, and renal dysfunction or failure[1,2] in patients undergoing coronary artery bypass graft (CABG) surgery.

A study entitled, "The Risk Associated with Aprotinin in Cardiac Surgery" by Mangano et al., was published in the *New England Journal of Medicine*, (Mangano D, Tudor J, Dietzel C. N Eng J Med, 2006 (354) :353-65. www.nejm.com). A study entitled, "A propensity score case-control comparison of aprotinin and tranexamic acid in high-transfusion-risk cardiac surgery" by Karkouti et al. has been published in the journal *Transfusion* (Karkouti K, Beattie W, Dattilo K, McCluskey S, Ghannam M, Hamdy A, et al., Transfusion, on-line edition, 1/20/06. www.blackwellpublishing.com/journal.asp?ref=0041-1132).

Relevant regulatory authorities have said that they will review these reports, data supplied by Bayer and the authors of the studies, other reports in the literature as well as adverse event reports submitted to health authorities through established regulatory processes, to determine if any actions are warranted. Several health authorities have or may issue guidance to physicians and patients in their respective markets. Bayer welcomes and supports both the review and evaluation of these published studies and

[1] Mangano et al, (NEJM, 1/26/06)
[2] Karkouti et al., (Transfusion, 1/20/06)

posting of guidance to physicians and patients in various markets. Bayer has posted and will mail letters to healthcare providers outlining background information concerning this issue.

Both studies were observational studies, and as such have certain methodological limitations, e.g. imbalances in baseline characteristics of patients which could result in the aprotinin-treated group being at higher risk to begin with for developing serious adverse events. This possibility prevents a direct assessment of whether aprotinin altered the risk for serious adverse events. To try to adjust for known differences between the treatment groups, the study authors used statistical procedures such as multivariable logistic regression and propensity score adjustments.

The *NEJM* publication studied patients undergoing coronary artery bypass graft (CABG) surgery who received either aprotinin or one of two other drugs intended to decrease perioperative bleeding. The authors reported an association of aprotinin with an increased risk of cardiovascular events (myocardial infarction or heart failure), cerebrovascular events such as stroke, encephalopathy or coma, and renal dysfunction or failure in these patients. The *Transfusion* study suggested that Trasylol administration increased the risk for renal dysfunction or failure. Renal dysfunction and renal failure have previously been reported in patients receiving Trasylol and is reflected in the current approved labeling for Trasylol. The *Transfusion* study authors did not find an increased rate of cardiovascular or cerebrovascular events in Trasylol-treated patients and reported comparable mortality rates between the control treatment group and the Trasylol group.

While the evaluation of these published reports and other relevant data continues, Bayer and various regulatory authorities have provided or indicated that they may soon provide guidance for physicians, other health care professionals and the public. The FDA has posted an "Alert for Healthcare Professionals" and a "Public Health Advisory" concerning Trasylol on its website (www.fda.gov) along with questions and answers related to this issue. Bayer has posted this statement and a letter to Healthcare Professionals on its websites today (www.bayer.com, www.bayerhealthcare.com, www.bayerpharma.com, www.bayervital.de and www.trasylol.com). In the next days Bayer will mail its letter to healthcare providers who use the product e.g. cardiothoracic surgeons, anesthesiologists and hospital pharmacists.

Guidance from regulatory authorities, e.g. the U.S Food and Drug Administration, (FDA) includes a recommendation that physicians carefully monitor patients receiving Trasylol for the occurrence of adverse events particularly related to the kidneys, heart,

or central nervous system and promptly report any events to Bayer or the relevant regulatory authorities. The guidance also suggests that while the evaluation continues, physicians should consider limiting Trasylol use to situations where the clinical benefit of reduced blood loss is essential for medical management of the patient and outweighs potential risks.

Bayer has been working and will continue to work closely with regulatory authorities in all countries where Trasylol is marketed to address questions regarding product safety. We share the company's data on Trasylol with regulatory authorities on an ongoing basis and welcome their evaluation of these published reports. Bayer believes that Trasylol is a safe and effective treatment when used in accordance with the product labeling.

About Trasylol

Trasylol, a broad-spectrum proteinase inhibitor, modulates the systemic inflammatory response associated with cardiopulmonary bypass (CPB) in the course of CABG surgery. Approved by the FDA in 1993, Trasylol is the only product indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing CPB in the course of CABG surgery. Full prescribing and warning information is also available at www.Trasylol.com. Trasylol Prescribing Information. Accessed on November 15, 2005. Available at: http://www.trasylol.com.

The effects of Trasylol use in CPB involves a reduction of inflammatory response to surgery, reduced bleeding and decreased re-exploration for bleeding, which translates into a decreased need for allogeneic (blood donated from another individual) blood transfusions. An important part of Bayer Pharmaceuticals Specialty Pharmaceuticals portfolio, Trasylol has remained a category leader for several years. Bayer is committed to further investment in the Trasylol franchise and is actively engaged in the research and development of a recombinant version of the product. In anticipation of emerging needs of this market, Bayer is also leading in next generation product development.

Important Safety Considerations

Anaphylactic or anaphylactoid reactions are possible when Trasylol is administered. Hypersensitivity reactions are rare in patients with no prior exposure to aprotinin. The risk of anaphylaxis is increased in patients who are reexposed to aprotinin-containing products. The benefit of Trasylol to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis should a second exposure to aprotinin be required (see WARNINGS and PRECAUTIONS in the Trasylol prescribing information).

In clinical studies, hypersensitivity and anaphylactic reactions were:

- rare (<0.1%) in patients with no prior exposure to Trasylol
- 2.7% overall reaction rate upon re-exposure
- within 6 months, the incidence was 5 percent
- after 6 months, the incidence was 0.9 percent

Trasylol is generally well tolerated. In clinical trials, graft patency, myocardial infarction, renal or hepatic dysfunction and mortality were comparable to placebo.

About Bayer HealthCare AG:
Bayer HealthCare, a subgroup of Bayer AG, is one of the world's leading innovative companies in the health care and medical products industry. In 2004, the Bayer HealthCare subgroup generated sales amounting to some €8.5 billion.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals, which was established as a new business entity on January 1, 2006, by combining the previous Pharmaceuticals and Biological Products Divisions. The new Pharmaceuticals Division comprises the Hematology/Cardiology, Primary Care and Oncology Business Units. Bayer HealthCare employs approximately 35,300 staff worldwide.

Our aim is to discover and manufacture innovative products that will improve human and animal health worldwide. Our products enhance well-being and quality of life by diagnosing, preventing and treating disease.

Leverkusen, February 8, 2006

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