# Bayer



Bayer AG !nvestor Relations 51368 Leverkusen Germany www.investor.bayer.com

### Investor News

### Bayer Acknowledges That New Trasylol Study Was Not Disclosed Prior to Recent FDA Cardio-Renal Advisory Committee Meeting

Leverkusen / October 1, 2006 – Bayer acknowledged today that it mistakenly did not inform the U.S. Food and Drug Administration about a retrospective study commissioned by the company to analyze the effects of aprotinin, aminocaproic acid and tranexamic acid in patients undergoing coronary artery bypass graft (CABG) surgery. This data was not shared immediately with the agency because it was preliminary in nature and raised significant questions on the study population, outcomes and methodology.

Bayer believes that despite the highly preliminary nature of this data, the information should have been shared with the FDA prior to the September 21<sup>st</sup> Advisory Committee meeting held to assess the safety and efficacy of Trasylol. This was a mistake on the company's part.

Bayer has submitted a copy of the preliminary report to the FDA and has notified other regulatory authorities. The company is now analyzing this report, answers received from the questions posed to the investigator, and additionally will work with the investigator and other experts to examine the underlying source data and fully understand the results.

Bayer is committed to patient safety. The company will continue to work closely with the FDA to address questions regarding this study and the overall safety and efficacy of Trasylol® (aprotinin injection).

#### Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry based in Leverkusen/Germany. In 2005, the Bayer HealthCare subgroup generated sales amounting to some 9.4 billion Euro. Bayer HealthCare employed 33.800 people worldwide in 2005.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Since January 1, 2006 the new Pharmaceutical Division consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

#### 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.

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 allogencic (blood donated from another individual) blood transfusions.

#### 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).

<sup>&</sup>lt;sup>1</sup> Trasylol Prescribing Information. Retrieved August 20, 2004 from <a href="http://www.trasylol.com">http://www.trasylol.com</a>.

In clinical studies, hypersensitivity and anaphylactic reactions were:

§ rate (<0.1%) in potients with no prior exposure to Trasylol

 $\S~2.7\%$  overall reaction rate upon re-exposure

o within 6 months, the incidence was 5 percent

o after 6 months, the incidence was 0.9 percent

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

Leverkusen, October 1, 2006

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#### Forward-looking Statements

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsnever to update these forward-looking statements or to conform them to future events or developments.

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## Investor News

Bayer MaterialScience: Costs of damage in Baytown not yet calculable

# Production restricted following explosion in TDI plant

Company declares state of force majeure

Baytown / September 29, 2006 – Following an explosion in a process vessel at the Baytown Industrial Park in the US state of Texas on Tuesday, September 26, 2006, Bayer Material Science is experiencing restrictions on production. An international team of experts from Bayer is working hard to investigate the cause of the incident in close collaboration with the responsible authorities.

Following the incident, one of Bayer MaterialScience's two TDI production lines in Baytown was shut down and will remain so temporarily. The damage in economic terms cannot yet be calculated. TDI (toluene diisocyanate) is used in the manufacture of flexible polyurethane foam which finds application, for example, in upholstery, mattresses and car seats.

The total annual capacity of Bayer MaterialScience's TDI production facilities in Baytown amounts to 200,000 metric tons. A good proportion of this comes from the production line that has been shut down. For this reason Bayer MaterialScience has declared a state of force majeure on Friday, September 29. The company will inform customers about this without delay.

Bayer Material Science currently continues to adhere to the targets it set for 2006.

With sales of EUR 10.7 billion in 2005, Bayer MaterialScience AG is one of the world's largest polymer manufacturers. Its main fields of activity are the production of high-tech polymer materials and the development of innovative solutions for products

used in many areas of everyday life. The main consumer sectors are the automotive, electrical/electronics, construction, sports and leisure industries. Bayer MaterialScience has production facilities at 40 sites around the world and a workforce of approx. 18,800. Bayer MaterialScience is part of the Bayer Group.

Leverkusen, September 29, 2006

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