

Bayer Temporarily Suspends Global Trasylol® Marketing

Leverkusen, Germany and West Haven, CT, USA – November 5, 2007 -- Following consultation with the German Federal Institute for Drugs and Medical Devices (BfArM), the U.S. Food and Drug Administration (FDA), Health Canada, and other health authorities, Bayer announced today that it has elected to temporarily suspend worldwide marketing of Trasylol® (aprotinin injection) until final results from the Canadian BART trial can be compiled, received and evaluated. The company took this global action following direction from the German BfArM and requests from the FDA and other regulators that Bayer temporarily suspend Trasylol marketing in their respective countries until final BART data were available. The BART study is an independent randomized, controlled trial being conducted in high-risk cardiac surgery patients.

Once the complete BART dataset is available, Bayer will work with health authorities to evaluate whether these data have any impact on the positive benefit-risk assessment for Trasylol. At that time the temporary marketing suspension will be reevaluated. Additionally, the U.S. FDA, Health Canada and other health authorities have indicated their interest in working with Bayer to create a program for use during the temporary suspension under which physicians in these markets might request and receive Trasylol for treatment of certain surgical patients with an established medical need. Bayer will work with the FDA, Health Canada, and any other authorities who wish to institute similar programs, to outline appropriate patient profiles and the specific details.

This action follows notification to Bayer and regulatory authorities that the BART Executive Committee had halted the trial after a planned periodic data analysis indicated reduced bleeding but also an increase in all-cause mortality (that almost reached conventional statistical significance for 30-day mortality) for patients in the aprotinin treatment arm compared to patients who received either aminocaproic acid or tranexamic acid. Bayer has been informed that data are now being collected from centers throughout Canada and a final data analysis will be undertaken by BART investigators -- a process that is expected to take up to eight weeks, or perhaps longer.

On October 25, 2007, Bayer posted additional guidance to physicians and health care providers regarding the use of Trasylol and BfArM, the FDA and other regulatory authorities posted health alerts and other communications in their respective markets. In the time since, the agencies have continued to work with Bayer to evaluate appropriate next steps. Given the limited and preliminary nature of the information available to date from the BART study, these are challenging and complex decisions.

To reiterate, once more complete information is available from BART investigators and a thorough evaluation can be conducted by Bayer and global health authorities, the company will communicate publicly regarding any further actions that may be undertaken in response to the analysis of that information. Over the next days, information concerning the temporary market suspension will be communicated to physicians, health care providers and hospital pharmacists in each respective market.

Bayer believes that the totality of the available data continue to support a favorable risk-benefit profile for Trasylol when used according to labeling.

First through third quarter estimated global 2007 revenue for Trasylol was €93 million, including approximately €63 million from the U.S. and €5 million in Germany.

Information regarding today's decision has been posted to Bayer's websites www.trasylol.com, www.pharma.bayer.com, www.bayerscheringpharma.de/trasylol/en, www.bayerhealthcare.com/trasylol/en, and the German BfArM, U.S. FDA and Health Canada have posted information on their respective web sites.

About Trasylol®

Trasylol is indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at an increased risk for blood loss and blood transfusion.

Trasylol administration may cause fatal anaphylactic or anaphylactoid reactions. Fatal reactions have occurred with an initial (test) dose as well as with any of the components of the dose regimen. Fatal reactions have also occurred in situations where the initial (test) dose was tolerated. The risk for anaphylactic or anaphylactoid reactions is increased among patients with prior aprotinin exposure and a history of any prior aprotinin exposure must be sought prior to Trasylol administration. The risk for a fatal reaction appears to be greater upon re-exposure within 12 months of the most recent prior aprotinin exposure. Trasylol should be administered only in operative settings where cardiopulmonary bypass (CPB) can be rapidly initiated. The benefit of Trasylol to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis associated with any subsequent exposure to aprotinin.

[\(See CONTRAINDICATIONS, WARNINGS and PRECAUTIONS in the prescribing information.\)](#)

Safety Considerations

Trasylol is contraindicated in patients with a known or suspected aprotinin exposure during the last 12 months. Aprotinin may also be a component of some fibrin sealant products.

In clinical studies, hypersensitivity and anaphylactic reactions were rare (<0.1%) in patients with no prior exposure to Trasylol.

Trasylol administration increases the risk for renal dysfunction and may increase the need for dialysis in the perioperative period.

This risk may be especially increased for patients with pre-existing renal impairment or those who receive aminoglycoside antibiotics or drugs that alter renal function.

The incidence of serum creatinine elevations >0.5 mg/dL above pre-treatment levels was statistically higher in the full-dose aprotinin group (9.0%) compared with placebo (6.6%).

The incidence of serum creatinine elevations >2.0mg/dL above baseline was slightly higher in the full-dose aprotinin group (1.1% vs. 0.8%).

In clinical trials Trasylol® did not increase the risk of the following perioperative events: myocardial infarction, congestive heart failure, hepatic dysfunction and mortality.

For Trasylol contraindications, warnings and precautions see prescribing information.

About Bayer HealthCare

Bayer HealthCare is a division of Bayer AG. One of the world's leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the U.S., Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, Specialized Therapeutics, Hematology/Cardiology and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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Forward-Looking Statement

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 annual and interim reports filed with the Frankfurt Stock Exchange. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.