Bayer

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Investor News

Bayer Temporarily Suspends Global Trasylol® Marketing

Leverkusen, 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 BART

According to information on the website of the Ottawa Health Research Institute (Institut de recherché en santé d'Ottawa), the BART study -- Blood Conservation using Antifibrinolytics: A Randomized Trial in High-Risk Cardiac Surgery Patients -- is a multi-institutional, blinded, randomized controlled trial to compare the efficacy and safety of the use of aprotinin, aminocaproic acid and tranexamic acid in approximately 3000 high-risk cardiac surgical patients undergoing either re-operation for coronary heart bypass graft (CABG) or aortic valve replacement, or combined valves or valve/CABG procedures.

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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