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ARRIVE Clinical Trial Methodology Presented at International Stroke Conference

Multi-national study will expand existing evidence of Aspirin benefits in preventing first stroke and heart attack moderate risk population

New Orleans (20 February, 2008) — The design and methodology of one of the largest studies of Aspirin ever conducted was presented today at the International Stroke Conference in New Orleans. Details of the ongoing ARRIVE trial (Aspirin to Reduce Risk of Initial Vascular Events) were shared by George Howard, M.D., Chairman, Department of Bio Statistics, University of Alabama School of Public Health in Birmingham, Ala., USA, the lead author of the abstract, and a member of the ARRIVE Executive Committee.

ARRIVE is a randomized, double-blind, placebo-controlled clinical trial assessing the efficacy and safety of daily 100mg enteric-coated Aspirin in preventing a first stroke or heart attack in patients at moderate risk. Moderate risk is defined as approximately 30% 10-year cardiovascular disease (CVD) event risk; or 10-20%, 10-year coronary heart disease (CHD) event risk. Because the ARRIVE trial is the first large trial to look specifically at a moderate risk patient population, this trial is expected to significantly expand the existing, strong body of evidence supporting use of Aspirin for the primary prevention of events associated with cardiovascular disease.

“Other studies of Aspirin have shown the safety and efficacy of Aspirin in primary prevention of cerebrovascular and cardiovascular events, but none have specifically looked at a patient population at moderate level of risk of a first event,” said Dr. Howard. “The ARRIVE study focuses on people who are at moderate risk; that is, have a yearly risk of a first event of approximately two percent. This information will help clinicians more fully understand the benefits of Aspirin in their moderate risk patients.”

ARRIVE Design and Methodology Details

The ARRIVE trial expects to recruit approximately 12,000 patients across 400 clinics in five countries: Germany, Italy, Spain, the United Kingdom and the United States. The primary study endpoint is a composite of cardiovascular death, myocardial infarction, and stroke. An event-driven termination design, set at 1,488 primary events, will provide over 90% power to detect a 15% treatment effect. It is estimated that study will take five years to achieve the necessary number of events. The expected study timeline includes enrollment completion Summer of 2009, trial termination in 2012, and results available in 2013.

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An innovative methodology was used to establish the entry criteria for selecting the moderate risk population to be studied in ARRIVE. The ARRIVE risk calculation methodology combines the elements of four existing risk calculator methods including Framingham and PROCAM for CHD, Framingham Stroke for stroke risk, and SCORE for cardiovascular death. It also estimates risk by accounting for differences that exist between low- and high-risk countries.

The primary entry criteria for the ARRIVE study are men aged 50 and older with two or three risk factors and women age 60 and over with three or more of the same risk factors. These risk factors include CVD risk factors including elevated total cholesterol and/or low HDL cholesterol, cigarette smoking, elevated blood pressure, current use of medication to control high blood pressure, and a family history of early CHD. Patients are ineligible if they have high or low CVD risk; are currently taking Aspirin therapy; are chronic or frequent users of non-steroidal anti-inflammatory drugs, COX-2 inhibitors, or metamizole; have a history of CVD; have risk of gastrointestinal (GI) or non-GI bleeding; are allergic to or have hypersensitivity to Aspirin; or have renal or hepatic impairment.

“With the ARRIVE trial, Bayer continues its commitment to work in partnership with the scientific community to advance initiatives that bring the benefits of Aspirin to a larger number of appropriate patients, and help reduce the global burden of cardiovascular disease,” said Wes E. Cetnarowski, M.D., Senior Vice President, Bayer Global Research & Development. “Certainly, most people have had personal family experience or know someone who was affected by cardiovascular disease. Information from ARRIVE could help patients and their physicians work more effectively to prevent a first CVD event.”

Heart Disease and Stroke

According to the World Health Organization, heart disease and stroke are the leading causes of death worldwide, accounting for 17.5 million, or 30 percent, of all deaths each year.⁸ By 2020, heart disease and stroke will become the leading cause of both death and disability worldwide.⁹ In addition, the related financial burdens are enormous; in the European Union alone, annual expenses associated with direct and indirect costs of all cardiovascular disease are estimated at 169 billion Euro (in 2006).¹⁰

Aspirin and CVD

Aspirin is approved in 36 countries for primary prevention of CVD events in at-risk patients. The benefits of Aspirin in secondary prevention have been demonstrated in more than 200 trials of 200,000 patients. Aspirin is approved worldwide for secondary prevention of CVD events. In addition, current clinical practice guidelines, including those issued by the American Heart Association and the European Society of Cardiology, among other major health organizations, advise physicians to consider Aspirin therapy for the appropriate patients.

About Bayer HealthCare

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The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Visit www.bayerhealthcare.com.

Visit www.arrive-study.com for additional information about the ARRIVE study.

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 whatsoever to update these forward-looking statements or to conform them to future events or developments.

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