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Investor News

Secondary Prevention in Acute Coronary Syndrome (ACS):

Bayer's Xarelto® Shows Encouraging Results in Patients with Acute Coronary Syndrome

- Phase II Data Presented as Late-Breaker at American Heart Association Meeting
- Phase III Study to be Initiated in December 2008

Leverkusen, November 10, 2008 – Findings from the ATLAS ACS TIMI 46 study – a Phase II study of the novel oral anticoagulant Xarelto® (rivaroxaban) – were presented today as a late-breaking clinical trial at the American Heart Association's Scientific Sessions 2008 in New Orleans by C. Michael Gibson, M.D., Director of the TIMI Data Coordinating Center, Harvard Medical School, Boston, Massachusetts, USA. Results from this Phase II study support moving rivaroxaban into a pivotal Phase III trial for the secondary prevention of acute coronary syndrome (ACS) later this year.

As a Phase II dose-finding study, the ATLAS ACS TIMI 46 trial was designed to test the safety and efficacy of rivaroxaban at escalating total daily doses, ranging from 5 mg up to 20 mg. Rivaroxaban was administered at once-daily and twice-daily intervals, assessing eight different dosing regimens in total. Nearly 3,500 patients were enrolled in the study and received standard antiplatelet therapy of low-dose aspirin with or without a thienopyridine, such as clopidogrel. Patients were then randomized to additionally receive either rivaroxaban or a placebo for six months.

"This was a robust study that achieved its main objective of establishing the preferred dosing scenario for further evaluating rivaroxaban in a large Phase III clinical trial of ACS patients," said Dr. Gibson. "The additional benefit of rivaroxaban over placebo in this study, given on a background of standard antiplatelet therapy, highlights the unmet medical need of this patient population."

The primary efficacy endpoint was death, myocardial infarction (MI), stroke, or severe recurrent ischemia requiring revascularization. Rivaroxaban was associated with an observed 21% Relative Risk Reduction (RRR) for the primary efficacy endpoint (p=0.1) and a statistically significant 31% RRR against the secondary endpoint of death, MI, or stroke (p=0.028), demonstrating a consistent trend for efficacy across doses.

Safety was evaluated by measuring clinically significant bleeding, defined as a composite of TIMI major bleeding, TIMI minor bleeding and any reported bleeding event requiring medical attention. This very sensitive bleeding measure represents a broader definition compared to other standard definitions. As expected, rivaroxaban-treated patients exhibited higher rates of bleeding vs. placebo when administered on a background of antiplatelet therapy, and there was a significant dose trend (p<0.001). However, no study arm was halted due to increased bleeding. Rates of clinically significant bleeding were: Placebo: 3.3%, rivaroxaban 5 mg: 6.1%, 10 mg: 10.9 %, 15 mg: 12.7%, 20 mg: 15.3%. Most bleeding (82%) was classified as bleeding requiring medical attention, rather than TIMI major or TIMI minor. No evidence of drug-induced hepatotoxicity was seen in the study.

Though not statistically significant due to the small sample size, the two doses selected for further evaluation in the pivotal Phase III program – 2.5 mg and 5 mg dosed twice daily – showed the best balance between efficacy and safety with an observed 46% RRR in the composite efficacy endpoint of death, MI or stroke when dosed in addition to aspirin, and an observed 45% RRR when dosed in combination with aspirin and a thienopyridine. Rates of TIMI major bleeding were 1.2% for each stratum.

ATLAS ACS TIMI 51

The global Phase III study, ATLAS ACS TIMI 51, is planned to be initiated in December 2008 with a potential enrollment of up to 16,000 patients. As in the Phase II study, all patients will receive standard antiplatelet therapy and will then be randomly assigned to take either rivaroxaban at doses of 2.5 mg or 5 mg, or placebo, twice daily for at least six months. The primary efficacy endpoint will be a composite of cardiovascular death, MI or stroke. TIMI major bleeding events not associated with coronary artery bypass graft (CABG) surgery will be the primary safety endpoint. A study overview will be accessible at www.clinicaltrials.gov.

“Given the encouraging response rates we saw in the ATLAS ACS TIMI 46 trial, we feel very confident in the two doses selected for evaluation in the Phase III study, and we are excited to progress Xarelto to the next level in our clinical development program for this important indication,” said Dr. Kemal Malik, Head of Global Development and member of the Board of Management of Bayer Schering Pharma AG.

About ACS

ACS occurs when a coronary artery is blocked by a blood clot, reducing blood supply to the heart. ACS events include MI, commonly known as heart attack, and unstable angina (a very serious condition that indicates a heart attack could soon occur). ACS is a common and life-threatening result of coronary heart disease (CHD), which kills approximately 7.2 million people worldwide each year.

“ACS is a chronic, life-threatening condition requiring daily therapy,“ said Study Chairman Eugene Braunwald, M.D., Distinguished Hersey Professor of Medicine at Harvard Medical School and Chairman of the TIMI Study Group. “While well-established therapies exist, there is a need for additional treatment options that could help improve patient outcomes. We look forward to initiating this pivotal study.”

About Xarelto® (rivaroxaban)

Xarelto is approved for use in the European Union for the prevention of VTE in adult patients who have undergone elective total hip or knee replacement surgery. Additional filings are under review with regulatory agencies in more than 10 other countries worldwide, including the United States.

The extensive clinical trial program supporting Xarelto makes it the most studied oral, direct Factor Xa inhibitor in the world today. With the addition of up to 16,000 patients in the Phase III ATLAS ACS TIMI 51 trial, over 60,000 patients are now expected to be enrolled into the Xarelto clinical development program, which will evaluate the product in the prevention and treatment of a broad range of acute and chronic blood-clotting disorders including VTE treatment, stroke prevention in patients with atrial fibrillation and VTE prevention in hospitalized, medically ill patients.

Xarelto was invented in Bayer’s Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

To learn more about thrombosis please visit www.thrombosisadviser.com and to learn more about Xarelto please visit www.xarelto.com

The complete ATLAS ACS TIMI 46 presentation can be accessed at www.timi.org.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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