Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Not intended for U.S. Media

Prevention of VTE in hospitalized, acutely ill patients:

In the Prevention of VTE in Acutely ill Patients, Rivaroxaban Compares Favorably with Enoxaparin but Does Not Show a Consistent Net Clinical Benefit

- MAGELLAN study meets primary efficacy endpoints of demonstrating non-inferiority in short-term use and superiority in long-term use
- Primary analysis shows no consistent positive benefit-risk balance across heterogeneous patient population studied

---

Leverkusen, April 5, 2011 – Findings from the MAGELLAN Phase III clinical study evaluating rivaroxaban for the prevention of venous thromboembolism (VTE) in hospitalized patients with acute medical illness were presented today at the 60th American College of Cardiology (ACC) Annual Scientific Session.

In the study, rivaroxaban met its primary efficacy endpoints of demonstrating non-inferiority to enoxaparin in short-term use (10 ± 4 days) and superiority to enoxaparin (10 ± 4 days) followed by placebo in long-term use (35 ± 4 days) in the prevention of VTE in hospitalized patients with acute medical illness. The rates of major plus non-major clinically relevant bleeding, the study's principal safety outcome, were low in both arms of the study, with unexpectedly lower rates observed in the enoxaparin arm compared to patients receiving rivaroxaban.

"MAGELLAN investigated the largest and most diverse population of hospitalized, acutely ill patients to date, and managing the risk of blood clots in these patients is extremely complex due to their age, co-morbid conditions and duration of immobilization. There is a continued risk of VTE beyond the initial period of hospitalization or immobilization in acutely ill patients," said Dr Alexander T. Cohen, MBBS MSc MD FRACP, King's College Hospital, London, UK, and principal investigator. "As observed in a previous study in this area, a consistently positive benefit-risk balance was not seen across the heterogeneous,

acutely ill patient population studied. Further analysis is required to identify which groups of patients in MAGELLAN may derive benefit from thromboprophylaxis with rivaroxaban."

In the MAGELLAN study, results for the primary efficacy endpoints (a composite of asymptomatic proximal DVT detected by ultrasonography, symptomatic DVT, non-fatal pulmonary embolism (PE), and VTE-related death) in the pre-specified study durations were as follows:

- In the short-term (10 ± 4 days) evaluation, rivaroxaban achieved non-inferiority compared to enoxaparin [2.7% vs. 2.7%, p=0.0025] in the per-protocol population.
- Evaluated in the extended period (35 ± 4 days), rivaroxaban was superior to short-term enoxaparin (10 ± 4 days) followed by placebo, in the modified intent-to-treat (MITT) population [4.4% vs. 5.7%, respectively, RR 0.77, p=0.0211].

The principal safety outcome was the incidence of treatment-emergent major bleeding events and non-major, clinically relevant bleeding events observed no later than two days after the last intake of the double-blind study drug. The rates of primary safety events were low overall in both arms of the study, but there was a statistically significant increase in patients randomized to rivaroxaban compared with patients in the enoxaparin arm on Day 10 (2.8% vs. 1.2%, respectively; p<0.0001) and on Day 35 (4.1% vs. 1.7%, respectively; p<0.0001). Rates of other adverse events, including liver and cardiovascular, were similar across both study arms and rates for rivaroxaban were in line with previous trial data.

About VTE in Medically ill Patients

Every year, venous blood clots kill more than 1 million people, including approximately 300,000 in the US and more than 500,000 in Europe[1]. VTE is often associated with recent surgery or trauma, but 50-70% of symptomatic thromboembolic events and 70-80% of fatal pulmonary embolism (PE) occur in non-surgical patients[2]. Hospitalization of acute medical illness is independently associated with an approximated eightfold increase relative risk for VTE[3], and accounts for almost one quarter of all VTE events in the general population[2].

Patients hospitalized due to acute illnesses often have multiple risk factors for VTE, which are generally cumulative[2]. Complete immobility is a major risk factor[2]. Other conditions commonly associated with hospitalization can increase the risk of VTE and include

congestive heart failure, acute respiratory disease, acute myocardial infarction, acute arthritis, acute infection, cancer and inflammatory bowel disease[2,4,5].

About the MAGELLAN Study

MAGELLAN was a multi-national, randomized, double-blind, placebo-controlled Phase III study investigating rivaroxaban for the prevention of VTE in patients admitted to hospital with an acute medical illness[6]. It evaluated 8,101 acutely ill medical patients from 52 countries, with a decreased level of mobility including at least one day of complete immobilization during hospitalization. MAGELLAN was designed to demonstrate the superior efficacy of a 35 ± 4 day treatment period with oral rivaroxaban (10 mg once daily) for VTE prophylaxis, compared to a 10 ± 4 day treatment period with subcutaneous enoxaparin (40 mg once daily) followed by placebo in men and women >40 years of age. Further, the study evaluated the non-inferiority of oral rivaroxaban for VTE prophylaxis compared to standard of care enoxaparin in this patient population at 10 ± 4 days.

The primary efficacy endpoints were a composite of asymptomatic proximal DVT detected by ultrasonography, symptomatic DVT, non-fatal pulmonary embolism (PE), and VTE-related death at Day 10 ± 4 and Day 35 ± 4, respectively. The principal safety endpoint was a composite of major bleeding and clinically relevant non-major bleeding[6] at Day 10 and Day 35.

The demographics and baseline characteristics were balanced between treatment groups. The groups were also equally balanced for acute medical conditions that were the reason for hospital admission.

About Rivaroxaban

Rivaroxaban is an oral anticoagulant that was invented in Bayer HealthCare's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for coagulation monitoring, as well as a limited potential for food and drug interactions.

Rivaroxaban is marketed under the brand name Xarelto® for VTE prevention in adult patients following elective hip or knee replacement surgery, and it is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin for this indication. Xarelto® is approved in more than 100 countries worldwide and has been successfully launched in more than 80 countries by Bayer HealthCare.

The extensive clinical trial program supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. More than 65,000 patients are participating in the rivaroxaban clinical development program evaluating the product in the prevention and treatment of a broad range of venous and arterial thromboembolic diseases, including stroke prevention in patients with atrial fibrillation, VTE treatment, and secondary prevention of acute coronary syndrome (ACS).

To learn more about thrombosis, please visit www.thrombosisadviser.com.

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 subgroup of Bayer AG with annual sales of EUR 16.913 billion (2010), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Find more information at www.bayerpharma.com.

<u>Bayer AG, Investor Relations contacts:</u>

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by the Bayer Group or subgroup 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 Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

References

1. Cohen AT, Agnelli G, Anderson FA et al. Venous Thromboembolism in Europe: The number of VTE events and associated morbidity and mortality. *Thromb Haemost*. 2007;98: 756-64
2. Geerts, WH et al. Prevention of Venous Thromboembolism: American College of Chest Physicians (ACCP); Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest* Jun 2008: 381-453
3. Heit, J.A., et al. Risk factors for deep vein thrombosis and pulmonary embolism: a population- based case-control study. *Arch InternMed* 2000; 160: 809–815.
4. Lyman G.H., et al. American Society of Clinical Oncology guideline: recommendations for venous thromboembolism prophylaxis and treatment in patients with cancer. *J Clin Oncol*. 2007; 25(34):5490-5505.
5. Francis, C.W. Clinical practice. Prophylaxis for thromboembolism in hospitalized medical patients. *N Engl J Med*. 2007;356(14):1438-1444.
6. Cohen, AT. Extended-duration rivaroxaban thromboprophylaxis in acutely ill medical patients: MAGELLAN study protocol. *J Thromb Thrombolysis* .