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Investor News

Patient Recruitment for Phase III Clinical Trial to Start in Studies of Oral Anticoagulant in Chronic Indications

Bayer and Ortho-McNeil, Inc. Outline Phase III Study Program of Oral Factor Xa Inhibitor Rivaroxaban in Chronic Indications

- Phase III studies in chronic indications to involve more than 20,000 patients
- Phase III trials to study stroke prevention in atrial fibrillation will begin patient recruitment during the coming weeks; phase III trials for the treatment of venous thromboembolism (VTE) will start recruiting in early 2007
- Based on the finalization of the study design, the companies are targeting a regulatory filing of rivaroxaban in these indications in 2010

Leverkusen / November 8, 2006 – After extensive discussions with the regulatory authorities in the U.S. and Europe, Bayer and Ortho-McNeil, Inc., a Johnson & Johnson company, have determined the final design of the phase III study program for the oral anticoagulant rivaroxaban in two chronic indications:

- Stroke prevention in atrial fibrillation (SPAF)
- Treatment and long-term secondary prevention of venous thromboembolism (VTE)

Stroke prevention in atrial fibrillation represents the largest potential indication, for which there exists substantial unmet medical need. The phase III program consists of one large, double-blind trial, which is designed to demonstrate non-inferiority of rivaroxaban against the current standard treatment of dose-adjusted warfarin. The principle investigator will be Robert Califf, M.D., director of the Duke Clinical Research Institute at the Duke University Medical Center, in Durham, North Carolina. The trial will include an estimated 14,000 patients, across 1,100 centres in more than

40 countries. This will be an event-driven study, meaning it will depend upon the occurrence of a statistically required number of strokes or systemic embolisms. After extensive dose-finding studies, the standard dose for rivaroxaban has been set at 20 mg once daily.

The VTE treatment program consists of two open label trials in patients with deep vein thromboembolism (DVT) and pulmonary embolism (PE) with a variable length of treatment up to 12 months against current standard treatment of low molecular weight heparin followed by dose-adjusted Vitamin-K antagonist. A third double-blind, placebo-controlled trial will analyze the value of prolonged treatment in this indication. The principle investigator for these trials is Harry Bueller, M.D., PhD, of the Academic Medical Center in Amsterdam. These event-driven studies will recruit about 7,500 patients, in about 300 centers in more than 20 countries. The study will use oral rivaroxaban for both the initial, intensified treatment phase as well as for the following period. The main dose of rivaroxaban will be 20mg once daily.

Currently, most anticoagulants are available only in injectable form, and as such are not suitable for use in long-term treatment. The only oral anticoagulant is warfarin, which requires frequent monitoring and interacts with numerous foods and other drugs.

"There currently exists significant medical need for an oral anticoagulant that does not require extensive and costly monitoring," said Kemal Malik, MD, Head of Global Development and Chief Medical Officer at Bayer HealthCare. "In studies conducted to date, rivaroxaban has demonstrated safety and efficacy across a wide range of doses and we look forward to the results of these studies."

Rivaroxaban is also currently in phase III trials in the prevention of venous thromboembolism, which are recruiting well. A first submission for marketing approval in this indication is planned for late 2007 in the EU and 2008 in the U.S. The global market for anticoagulants is currently estimated to be worth $5.7 billion (USD) and is forecast to grow at a double-digit percentage rate each year.

About Rivaroxaban

Rivaroxaban is a novel, oral, direct Factor Xa inhibitor that could potentially reduce the risk of life-threatening thromboembolic events. Factor Xa, the target enzyme, is a protease that acts to hinder blood clotting at the pivotal point in the coagulation cascade, the process that leads to clot formation.

Published results show that rivaroxaban offers predictable anticoagulation across a wide range of parameters, which strongly suggests that routine coagulation monitoring will not be required. In addition, data also show that rivaroxaban does not interact with a wide variety of drugs that are commonly given concomitantly with an anticoagulant.

Phase III trials with rivaroxaban in the prevention of venous thromboembolism (VTE) following major orthopedic surgery are already ongoing. The RECORD trial program (**RE**gulation of **C**oagulation in **OR**thopedic surgery to prevent **D**VT and PE) began in December 2005.

Bayer HealthCare is developing this antithrombotic compound jointly with Ortho-McNeil Pharmaceuticals Inc., a subsidiary of Johnson & Johnson.

Bayer HealthCare
Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry based in Leverkusen/Germany. In 2005, the Bayer HealthCare subgroup generated sales amounting to some 9.4 billion Euro. Bayer HealthCare employed 33.800 people worldwide in 2005.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Since January 1, 2006, the new Pharmaceutical Division consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

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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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Further integration measures determined:

Global R&D organization for future Bayer Schering Pharma defined

- Global R&D units in Berlin and Wuppertal, Germany, and Berkeley, California
- U.S. headquarters of Bayer Schering Pharma to be located in Wayne and Montville, New Jersey
- Recommendations already made for some 70 Bayer Schering Pharma sites

Leverkusen / November 9, 2006 – Bayer is proceeding apace with the integration of Schering. In recent weeks, managerial positions in the future Bayer Schering Pharma have been appointed as far down as the third hierarchy level, and three further major decisions have now also been made following the registration of the control and profit-and-loss transfer agreement in the Commercial Register. For example, the structure of Bayer Schering Pharma's global research and development organization has been defined and a reorganization of the U.S. sites has been initiated. In addition, Bayer AG's Board of Management has agreed on a concept for the future for some 70 Bayer Schering Pharma sites, including some in Germany. The concrete measures will be implemented in accordance with the local legal requirements.

As part of this change, research programs and activities now dispersed in various sites will be consolidated into three major research and development sites: Berlin and Wuppertal in Germany and Berkeley in California, U.S. "The changes in Research and Development will leverage the combined assets of Schering and Bayer to maximize both the output and effectiveness of our global drug discovery and development programs. They also give us the flexibility to substantially lower our ongoing infrastructure costs," said Arthur Higgins, Chairman of the Board of Bayer HealthCare AG and Chairman of the Board of Management of the future Bayer Schering Pharma AG.

The Berlin research group will take leadership for Diagnostic Imaging, Oncology and Gynecology/Andrology research and Wuppertal will be core for the company's Cardiology research. Both locations have significant capabilities and activities in target discovery, lead generation and optimization, drug metabolism and pharmacokinetics, toxicology and clinical pharmacology.

Berkeley will remain an important global R&D center for protein-based biologics drug discovery and will continue to be home of the state-of-the-art Kogenate biological manufacturing facility. This facility is strategically located in the world's most active biotech corridor, and therefore it is expected to become a research center of excellence and anchor for continuing work in hematology as well as in immunology and inflammation. In addition, the site in California will also remain the headquarters for the global Hematology/Cardiology business unit. Leukine, a growth factor for white blood cells, will continue to be manufactured in the Puget Sound Region in the state of Washington.

The consolidation means that the Bayer HealthCare's U.S. research site in West Haven, Connecticut, and that of Berlex Inc. (U S. subsidiary of Schering) in Richmond, California, will be closed. Bayer Pharma will relocate remaining departments and functions presently based in West Haven into headquarters locations in New Jersey.

Wayne and Montville, New Jersey will be headquarters for the company's U.S. pharmaceutical commercial operations and Global Oncology and Specialized Therapeutics business units, and home to U.S.-based Global Drug Development groups and other business support functions. Employee groups transferring from other U.S. sites will move over the next 12-18 months.

The company anticipates the consolidation of research activities to be largely complete by the end of the first half of 2007. Bayer anticipates that approximately 600 U.S. positions will be eliminated by these changes, primarily in research. Over time it is anticipated to eliminate an additional 200 U.S.-based positions by the overall reorganization. After one-time costs of approximately US$350 million, of which approximately US$200 million are non-cash related, these measures will enable the company to reduce overall R&D costs by over US$210 Million per year by the end of 2008. Bayer expects synergies totaling EUR 700 million to be achieved from the year 2009.

Further reorganization outside the United States

Schering's present German sales organization, which is based in Berlin, is set to relocate to Leverkusen, where Bayer HealthCare's German sales function, Bayer Vital, is based. In addition, it is also planned to relocate two units of Bayer HealthCare's Pharmaceuticals Division from Wuppertal and Leverkusen to the future headquarters of Bayer Schering Pharma in Berlin. The areas in question are the Primary Care business unit and the European sales units for Oncology and Hematology/Cardiology.

Measures affecting the sites in Germany will now be implemented, as in the other countries, in accordance with the relevant legal requirements. It is not yet possible to issue concrete statements on headcounts and schedules.

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