Bayer

Investor News

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Prevention of Thromboembolism after Knee Replacement Surgery:

Rivaroxaban One Tablet/Once-Daily Superior to Twice-Daily Injectable Enoxaparin in Preventing Venous Blood Clots after Total Knee Replacement Surgery in Pivotal Phase III Trial

- Rivaroxaban is First Oral Anticoagulant to Achieve Superior Efficacy over the Twice-Daily Injection of Enoxaparin while Maintaining Low Major Bleeding Rates
- RECORD4 Confirms Results of RECORD1, 2 and 3
- U.S. Submission Planned for mid 2008
- Prof. Turpie: “Rivaroxaban has the potential to revolutionize the way we prevent the formation of dangerous blood clots”

Leverkusen, May 30, 2008 – Phase III clinical trial results demonstrate that rivaroxaban (Xarelto®), a one tablet/once-daily, oral investigational anticoagulant, showed superior efficacy in preventing venous blood clots in patients following total knee replacement (TKR), whilst maintaining low major bleeding rates. The RECORD4 study compared rivaroxaban with the U.S.-approved treatment regimen for injectable enoxaparin, a current standard of care.

Data from RECORD4 were presented today at the 9th Annual Meeting of the European Federation of National Associations of Orthopaedics & Traumatology (EFORT) in Nice, France. Rivaroxaban is being jointly developed by Bayer HealthCare AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

The RECORD4 data show that rivaroxaban (10mg tablet once-daily) provided TKR surgery patients with a statistically significant reduction of total venous thromboembolism (VTE) event rates over twice-daily injectable enoxaparin (6.9% and 10.1%, respectively; p = 0.012). This corresponds to a 31% relative risk reduction (RRR) over enoxaparin

(30mg injection twice-daily). The rate of major bleeding in the rivaroxaban-treated patients was low and not statistically different to the rate of major bleeding in the enoxaparin-treated patients (0.7% and 0.3%, respectively; p=0.110).

While the RECORD1, 2 and 3 studies compared rivaroxaban against enoxaparin 40mg injected once-daily to reduce blood clots after major orthopaedic surgery, RECORD4 is the first trial to evaluate rivaroxaban against enoxaparin 30mg injected subcutaneously twice-daily, which is the U.S. Food and Drug Administration (FDA)-approved treatment regimen for enoxaparin. RECORD4 provides additional head-to-head trial evidence demonstrating superior efficacy of rivaroxaban compared to enoxaparin together with a similar low rate of major bleeding, and establishes rivaroxaban as the first oral anticoagulant to show superiority over this regimen of enoxaparin.

“The superior efficacy and similar adverse event profile of rivaroxaban demonstrated in RECORD4 are in line with the outstanding results of the earlier RECORD studies," said Dr. A.G.G. Turpie, Professor of Medicine, McMaster University, Canada and Principal Investigator for the RECORD program. “The success of this trial strengthens my belief that direct Factor Xa inhibition with rivaroxaban has the potential to revolutionize the way we prevent the formation of dangerous blood clots.”

RECORD4 is part of the RECORD program (REgulation of Coagulation in major Orthopedic surgery reducing the Risk of DVT and PE), which involved more than 12,500 total hip or knee replacement surgery patients. The full RECORD data set will be used to support the new drug application for rivaroxaban in the U.S. which is planned for submission in mid 2008.

“We are very pleased that rivaroxaban has once again exceeded our expectations", said Frank Misselwitz, MD, Head of Cardiovascular Development, Bayer HealthCare AG. "RECORD4 is a testament to the outstanding, robust and consistent results we have seen across the full RECORD program."

RECORD4 Study Details

RECORD4 compared rivaroxaban with enoxaparin for the prevention of VTE following TKR surgery in 3,148 patients. Rivaroxaban (10mg tablet once-daily) was administered 6-8 hours post surgery, compared to enoxaparin (30mg injection twice-daily) which was administered 12-24 hours post surgery, in accordance with the U.S.-approved regimen.

The study demonstrated a 31% RRR in total VTE, the primary endpoint of this trial (composite of deep vein thrombosis, non-fatal pulmonary embolism and all-cause mortality), for patients treated with rivaroxaban compared with those treated with enoxaparin (6.9% and 10.1%, respectively; p=0.012). Event rates for secondary endpoints were consistently lower in the rivaroxaban-treated patients, but did not reach statistical significance.

Notes to editors:

Unmet Needs in Venous Thromboembolism (VTE)
In the EU, venous blood clots are associated with more than 1.5 million events annually, and are responsible for killing 544,000 individuals each year – more than breast cancer, prostate cancer, HIV/AIDS and road traffic accidents combined.

VTE is a serious life-threatening condition. It includes deep vein thrombosis (DVT) – a blood clot in a deep vein (usually in the leg) – and pulmonary embolism (PE) – a blood clot in the lungs. These clots often break apart and travel through the bloodstream, blocking blood flow to vital organs. During hip or knee replacement procedures, the large veins of the leg that carry blood back to the heart are damaged which significantly increases the VTE risk for patients undergoing such major orthopedic surgery. In fact, venous blood clots occur in 40-60% of patients undergoing major orthopedic surgery and not receiving preventative care.

An estimated 815,000 hip replacement procedures were performed in the U.S. and Europe in 2005, while the number of knee replacement procedures was estimated to be 761,000. But the threat stretches beyond orthopedic surgeries: Blood clots are one of the leading causes of global disease and death in many patient populations, including those with atrial fibrillation at risk for stroke, those at risk for acute myocardial infarction (heart attack) and acutely ill hospitalized patients, such as those with cancer.

About the RECORD Study program
RECORD is a global program of clinical trials involving more than 12,500 patients, comparing rivaroxaban with injectable enoxaparin for the prevention of VTE in patients undergoing either total knee or hip replacement surgery.

- In RECORD1, rivaroxaban demonstrated a 70% relative risk reduction (RRR) in total VTE in patients undergoing total hip replacement (THR) surgery compared with

enoxaparin, with a similar safety profile. The duration of thromboprophylaxis in both treatments was five weeks.

- In RECORD2, extended-duration rivaroxaban (35+/-4 days) demonstrated a 79% RRR in total VTE and a similar rate of major bleeding in patients undergoing THR surgery compared to patients dosed with short-duration therapy with enoxaparin (10–14 days) followed by placebo.
- In RECORD3, rivaroxaban demonstrated a 49% RRR in total VTE in patients undergoing total knee replacement (TKR) surgery compared to enoxaparin, with a similar safety profile. Both treatments were dosed for 10–14 days.
- In RECORD4, 10mg once-daily rivaroxaban was compared to the U.S.-approved regimen for enoxaparin of 30mg injected twice-daily. Rivaroxaban demonstrated a 31% RRR in total VTE in patients undergoing TKR surgery compared to enoxaparin, with a similar safety profile. Both treatments were continued for 10–14 days.

About Rivaroxaban

Rivaroxaban is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. The extensive clinical trial program for rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. Based on the clinical evidence in more than 20,000 patients, rivaroxaban has not been associated with compromised liver function. A more definitive statement will be made once the data from long-term exposure to rivaroxaban in the VTE treatment and stroke prevention in atrial fibrillation (SPAF) programs is available. Almost 50,000 patients are expected to be evaluated in the total clinical development program.

Bayer HealthCare submitted a regulatory filing to the European Agency for the Evaluation of Medicinal Products (EMEA) at the end of October 2007 for approval to market rivaroxaban in the EU for the prevention of VTE in patients undergoing major orthopaedic surgery of the lower limbs. To date, the drug has been filed in more than 10 countries, including Canada and China, and is also expected to be filed for approval in the U.S. in mid 2008, where upon approval it will be commercialized by Scios Inc. and Ortho-McNeil, Inc., both of which are wholly-owned subsidiaries of Johnson & Johnson.

The trade name of rivaroxaban is expected to be Xarelto®, pending health authority approval.

Please visit www.thrombosisadviser.com for more information on VTE.

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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