Bayer

Investor News

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

New Drug Application for Rivaroxaban in the U.S.:

Update on Status of Rivaroxaban Complete Response Letter From U.S. FDA

Leverkusen, July 14, 2009 – Bayer Schering Pharma AG, Germany, announced today that its partner, Ortho-McNeil, does not expect to submit its complete response to the U.S. Food and Drug Administration (FDA) until the fourth quarter of this year, at the earliest.

“We are fully convinced of the positive risk-benefit profile of rivaroxaban, which has been approved in more than 60 countries worldwide in its first indication, and there are no new data in the clinical trials database that would change this assessment,” said Kemal Malik, member of the Bayer HealthCare Executive Committee and Chief Medical Officer. “We want to take the time to diligently respond to all the questions raised by the FDA in the Complete Response Letter and are confident that, together with our partner, Ortho-McNeil, we can provide all information necessary for an approval of rivaroxaban in the U.S.”

While no new clinical or non-clinical studies to evaluate the efficacy or safety of rivaroxaban were requested by the FDA as a pre-requisite for approval, the FDA has asked the company to submit additional data from completed and ongoing studies of rivaroxaban, and from market surveillance from those countries outside the U.S. where the drug is currently sold to further assess the risk-benefit profile of the drug. The FDA also asked for additional information on RECORD study sites.

Additional meetings between Ortho-McNeil and the FDA are planned this summer to agree on a plan to adequately address the points raised by the FDA in its complete response letter. The outcome of those discussions will be a key determinant in establishing the eventual timeline for submission of the complete response.

Rivaroxaban is a novel, oral anticoagulant currently under FDA review as one tablet, once-daily for the prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery. The NDA for rivaroxaban was submitted by Johnson & Johnson Pharmaceutical Research & Development, L.L.C., on behalf of Ortho-McNeil Inc., on July 28, 2008. In March 2009, an FDA Advisory Committee agreed by a vote of 15-2 that the available clinical data for rivaroxaban demonstrated a favorable risk-benefit profile.

If approved by the FDA, Ortho-McNeil, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company), will commercialize rivaroxaban in the U.S. The U.S. Bayer HealthCare sales force will support the Ortho-McNeil sales force by detailing rivaroxaban in designated hospital accounts. Bayer HealthCare is exclusively responsible for the marketing of rivaroxaban in countries outside the U.S.

Unmet Needs in Venous Thromboembolism (VTE)

Blood clots can break apart and travel through the bloodstream, blocking blood flow to vital organs. VTE includes DVT, a blood clot in a deep vein (usually in the leg), and PE, a blood clot in the lung, both of which are serious, life-threatening – but often preventable – conditions. Patients undergoing major orthopedic surgery are at high risk for VTE because during hip or knee replacement procedures, the large veins of the leg that carry blood back to the heart can be damaged, significantly increasing the risk of developing a clot. In fact, venous blood clots occur in 40-60 percent of patients undergoing major orthopedic surgery who do not receive preventive care. Each year, approximately 800,000 Americans elect to have hip or knee replacement surgeries, and VTE is the most common cause of re-hospitalization for this patient group.

About rivaroxaban

Rivaroxaban 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. Rivaroxaban is approved in the European Union for the prevention of VTE in adult patients undergoing elective hip or knee replacement surgery, where it is marketed under the brand name Xarelto®. Additional approvals have been granted in other countries, including Australia, Canada, China, Mexico and Singapore. To date, Xarelto® has been launched in more than 40 countries around the world 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 expected to be enrolled into the rivaroxaban 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, secondary prevention of acute coronary syndrome, and VTE prevention in hospitalized, medically ill patients.

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 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. 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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Ilia Kürten (+49-214-30-35426)
Ute Menke (+49-214-30-33021)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by 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.