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Investor News

Not intended for U.S. and UK media

FDA Approves Xarelto® (rivaroxaban tablets) for the Prophylaxis of Deep Vein Thrombosis Which May Lead to a Pulmonary Embolism in Patients Undergoing Knee or Hip Replacement Surgery

Xarelto® is the only new oral anticoagulant with US approval in this indication

Leverkusen, July 1, 2011 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has approved Xarelto® (rivaroxaban tablets), the first once-daily, oral anticoagulant for the prophylaxis of deep vein thrombosis (DVT) which may lead to a pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery. Xarelto® is approved for use at a 10 mg dose, one tablet, once-daily for 35 days following hip replacement and for 12 days following knee replacement surgery. Xarelto® is the only new oral anticoagulant with US approval in VTE prophylaxis for patients undergoing knee or hip replacement surgery.

“The approval of once-daily Xarelto® tablets will provide a new option to help protect patients in the US from developing venous blood clots following knee or hip replacement surgery,” said Louis M. Kwong, M.D., professor of orthopedic surgery at Harbor-UCLA Medical Center, who was involved with the rivaroxaban clinical trial program in this indication. “Xarelto® has a proven clinical benefit over one of today’s most widely used options in preventing these potentially life-threatening blood clots, and the use of a once-daily pill may play an essential role in helping to simplify clinical practice.”

According to the American Academy of Orthopedic Surgeons, more than 800,000 Americans undergo knee or hip replacement surgery each year. These procedures are associated with an increased risk for DVT, a blood clot that forms in a deep vein, usually in the leg. If all or part of a DVT breaks off, it can travel to the lungs and cause a PE, where it may impact the flow of oxygenated blood and lead to potentially life threatening consequences.

The American College of Chest Physicians recommends the use of blood thinners (anticoagulants) immediately following knee or hip replacement surgery and extended use post-discharge (at least 10 days for knee replacement, and up to 35 days for hip replacement) to help reduce such risks. However, full compliance with these guidelines using previously available options has not been widely observed. DVT and PE are the leading causes of re-hospitalization following joint replacement surgery.

“The use of blood thinners has been shown to safely and effectively help people from developing preventable blood clots,” said Alan Brownstein, Chief Executive Officer of the National Blood Clot Alliance. “The FDA approval of a new blood thinner, Xarelto®, offers a new option for patients seeking knee or hip replacement surgery, and we encourage people to discuss with their physicians the risk of blood clots and which blood thinner offers optimal protection as part of their pre-surgical consultation.”

Phase III data from the Xarelto® clinical development program showed superior efficacy of rivaroxaban, both in head-to-head comparison with enoxaparin and when comparing extended-duration (5 weeks) rivaroxaban with short-duration (2 weeks) enoxaparin followed by placebo. In these trials, rivaroxaban and enoxaparin demonstrated similar safety profiles including low rates of major bleeding.

About Xarelto® (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. To date, Xarelto® is approved in more than 110 countries worldwide and has been successfully launched in more than 80 countries by Bayer HealthCare in this indicaton. In the U.S., Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights for Xarelto®. Bayer HealthCare sales force will support the Janssen Pharmaceuticals, Inc. sales force by detailing Xarelto® in designated hospital accounts.

The extensive clinical trial program supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies, reported and ongoing, involve over 65,000 patients for the prevention and treatment of venous and arterial thromboembolic disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with atrial fibrillation, VTE treatment, and the secondary prevention of acute coronary syndrome.

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.

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