About the ROCKET AF Study

Fast facts

- **ROCKET AF is a major double-blind event-driven outcomes study in stroke prevention comparing the safety and efficacy of once-daily, oral rivaroxaban and the vitamin K antagonist (VKA), warfarin, in patients with non-valvular atrial fibrillation (AF)**
- **ROCKET AF is the first study to report on the benefit-risk profile of a once-daily Factor Xa inhibitor versus the current standard of care in stroke prevention in AF (SPAF)**
- **14,269 patients have been randomized from more than 1,330 sites across 45 countries**
- **The trial specifically assesses patients with AF most in need of anticoagulation, (typical of those seen in clinical practice) especially as an alternative to VKA therapy**

What is the ROCKET AF trial?

ROCKET AF is a Phase III major outcomes study to compare the efficacy and safety of once-daily, oral rivaroxaban with warfarin for the prevention of stroke in patients at increased risk of stroke.

ROCKET AF: Rivaroxaban Once-daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for the prevention of stroke and Embolism Trial in Atrial Fibrillation	
Study design	◆ Randomized, double-blind, event-driven trial (more than 1,330 centers across 45 countries worldwide)
Interventions	◆ Once-daily, oral rivaroxaban 20 mg (15 mg once-daily for patients with moderate renal impairment at screening) ◆ Warfarin once-daily titrated to an International Normalized Ratio of 2-3
Number of patients	◆ 14,269
Study inclusion criteria	◆ Documented non valvular AF ◆ Prior stroke, or transient ischemic attack (TIA), or systemic embolism or at least 2 of the following: • Congestive heart failure or LVEF ≤35% • Hypertension • Age ≥75 years • Diabetes mellitus
Primary efficacy endpoint	◆ Composite of stroke and non-CNS (central nervous system) systemic embolism (blood clots occluding vessels outside the brain)
Primary safety endpoint	◆ Composite of major and non-major clinically relevant bleeding events

Trial Attributes	
Patients eligible for anticoagulation according to guidelines	◆ Patients recruited were at moderate to high risk for stroke (CHADS2 ≥ 2)* who are in need for anticoagulation and for whom anticoagulation therapy with warfarin is recommended according to current guidelines
Primary and secondary prevention of stroke	◆ Approximately half of patients included in the study have a history of stroke, transient ischemic attack (TIA), or systemic embolism ◆ Therefore, the ROCKET AF trial population allows for the assessment of the clinical benefit of rivaroxaban for both primary and secondary prevention of stroke in AF patients
Age	◆ AF is more prevalent among the elderly; this age group is frequently under-treated with current therapies and often under-represented in clinical trials ◆ Study population had a higher mean age than other trials in this disease area (73.1 years) with 44% of patients 75 years or older
Benefit-risk	◆ The risk of bleeding will be assessed in the primary safety endpoint of ROCKET AF ◆ ROCKET AF will allow a thorough assessment of benefit-risk in a relevant patient population

*$CHADS_2$ score is a clinical prediction rule for estimating the risk of stroke in patients with AF; a higher $CHADS_2$ score corresponds to a higher risk of stroke

About Rivaroxaban

Rivaroxaban is a novel oral anticoagulant that was invented in Bayer Schering Pharma's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. In clinical studies, rivaroxaban has been shown to be effective in preventing VTE in adult patients following elective hip or knee replacement surgery. 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 new 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 75 countries by Bayer Schering Pharma achieving the market leader position among the new oral anticoagulants.

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 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

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RIVAROXABAN

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