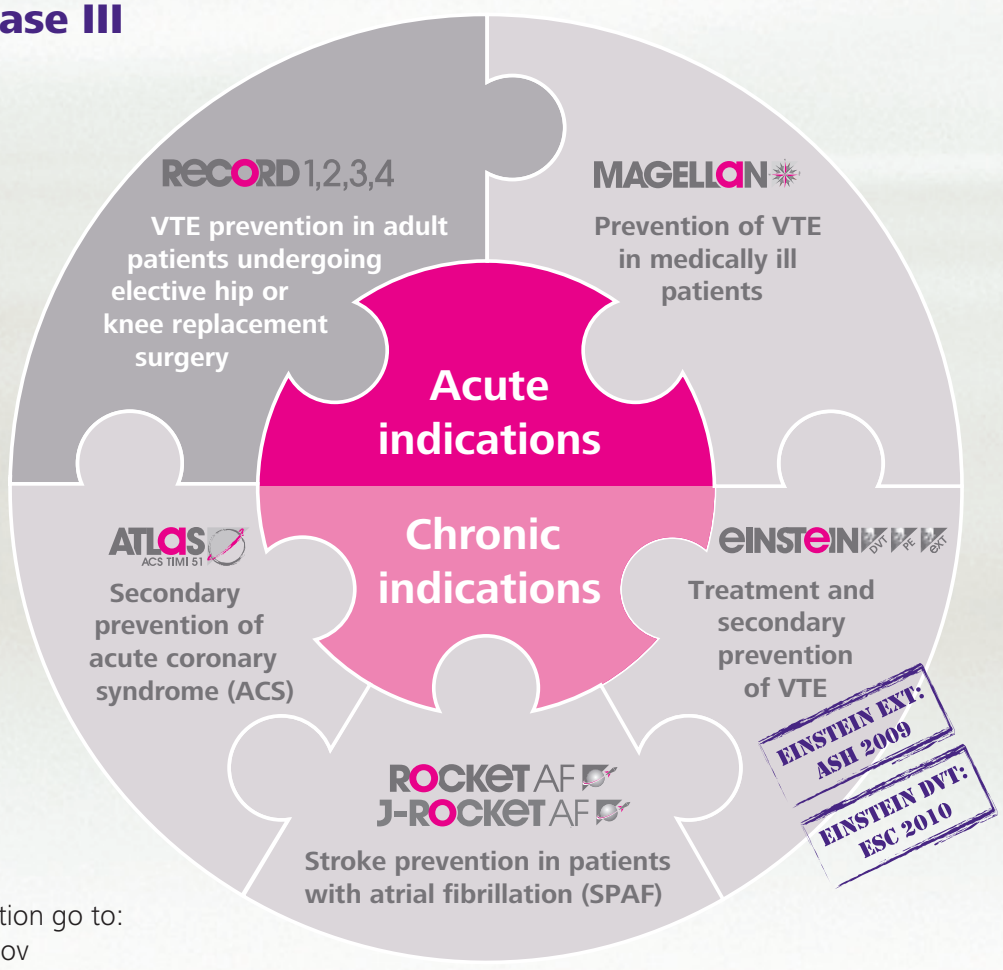
About the Rivaroxaban Clinical Trial Program

Leading the Way in Oral, Direct Factor Xa Inhibition

Fast facts

- **Xarelto® (rivaroxaban) is a once-daily, oral, direct Factor Xa inhibitor in advanced clinical development for a wide range of indications and patients who could benefit from the prevention and/or treatment of potentially deadly blood clots**
- **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**

Extensive Phase III Program



Completed

Ongoing

For further information go to:
www.clinicaltrials.gov

Bayer HealthCare
Bayer Schering Pharma

RIVAROXABAN

MEDIA BACKGROUNDER
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August 2010

Indication	Study Program	Patients	Primary End Points	Outcome
Acute Indications				
Primary prevention of VTE: Hip Replacement Surgery NCT00329628 and NCT00332020	RECORD 1	4,541	Efficacy; composite of: ◆ Deep vein thrombosis (DVT) ◆ Non-fatal pulmonary embolism (PE) ◆ All-cause mortality Safety: ◆ Major bleeding	Superior efficacy*, comparable safety. *NEJM,* 2008
	RECORD 2	2,509		Superior efficacy**, comparable safety. *The Lancet,* 2008
Primary prevention of VTE: Knee Replacement Surgery NCT00361894 and NCT00362232	RECORD 3	2,531		Superior efficacy*, comparable safety. *NEJM,* 2008
	RECORD 4	3,148		Superior efficacy*, comparable safety. *The Lancet,* 2009
VTE Prevention: Hospitalized, Medically Ill Patients NCT00571649	MAGELLAN	~8,000	Efficacy; composite of: ◆ Asymptomatic proximal DVT ◆ Symptomatic DVT ◆ Non-fatal PE and VTE-related death Safety: ◆ Composite of major and non-major clinically relevant bleeding	Ongoing
Chronic Indications				
Treatment of Deep Vein Thrombosis (DVT) NCT00440193	EINSTEIN DVT	3,449	Efficacy: ◆ Symptomatic recurrent VTE – the composite of recurrent DVT, fatal or non-fatal PE Safety; composite of: ◆ PE & DVT: Major and non-major clinically relevant bleeding events ◆ EXT: Major clinically relevant bleeding events	Recruitment complete – results expected 2010 EINSTEIN DVT: ESC 2010
Treatment of Pulmonary Embolism (PE) NCT00439777	EINSTEIN PE	~4,000		Recruitment ongoing
Secondary Prevention of Venous Blood Clots (VTE) NCT00439725	EINSTEIN EXT	1,197		Superior efficacy***, low major bleeding rates EINSTEIN EXT: ASH 2009
Stroke Prevention in Atrial Fibrillation (SPAF) NCT00403767	ROCKET AF	~14,000	Efficacy; composite of: ◆ Stroke ◆ Non-CNS systemic embolism Safety; composite of: ◆ Major and non-major clinically relevant bleeding events	Recruitment complete – results expected 2010‡
	J-ROCKET AF	1,280		Recruitment complete – results expected 2010‡
Secondary Prevention in Acute Coronary Syndrome NCT00809965	ATLAS ACS TIMI 51	~16,000	Efficacy; composite of: ◆ CV death, MI, or stroke Safety; composite of: ◆ Major (non CABG TIMI) bleeding	Ongoing

* Superiority vs. enoxaparin
** Extended duration with rivaroxaban more effective than short-term therapy with enoxaparin
*** Superiority vs. placebo
‡ Please note that these timings may be subject to change as the studies progress

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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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