



Rivaroxaban Significantly Reduces Risk of Stroke in Patients with Atrial Fibrillation with Comparable Safety vs. Warfarin in Pivotal Phase 3 Study

Results Presented as a Late-Breaker at the Scientific Sessions of the American Heart Association

CHICAGO, NOVEMBER 15, 2010 - Johnson & Johnson Pharmaceutical Research & Development, L.L.C. announced today that results from the pivotal Phase 3 double-blind ROCKET AF trial showed rivaroxaban given once daily was superior in reducing the risk of stroke and non-CNS systemic embolism in patients with atrial fibrillation (AF) with comparable safety versus warfarin, the most commonly used medicine for the prevention of stroke in AF patients.¹

In the study, rivaroxaban was superior to warfarin for the primary efficacy endpoint, showing a 21% relative risk reduction (RRR) for stroke and non-CNS systemic embolism in the pre-specified on-treatment population² (1.7%³ vs. 2.2%, respectively, $p=0.015$). Additionally, in the intent to treat population (ITT),⁴ which followed all patients randomized in the trial until its completion, whether or not they completed the full course of therapy or switched to other options, rivaroxaban showed comparable benefits to warfarin (2.1% vs. 2.4%, $p<0.001$ for non-inferiority). This result indicates that the treatment benefits compared to warfarin were sustained as long as the patients received rivaroxaban.

Rivaroxaban-treated patients also had numerically fewer myocardial infarctions (0.9% vs. 1.1%, $p=0.121$), and an observed reduction in rates of all-cause mortality compared to warfarin (1.9% vs. 2.2%, $p=0.073$), though these results were not statistically significantly different.

For the principal safety measure, rivaroxaban showed similar rates of major⁵ and non-major clinically relevant bleeding events,⁶ compared to warfarin (14.9% vs. 14.5%, $p=0.442$). Rates of major bleeding were also comparable between rivaroxaban and warfarin (3.6% vs. 3.5%, $p=0.576$). Patients treated with rivaroxaban had fewer intracranial hemorrhages (0.5% vs. 0.7%, $p=0.019$), critical organ bleeds (0.8% vs. 1.2%, $p=0.007$) and bleeding-related deaths (0.2% vs. 0.5%, $p=0.003$) compared to those treated with warfarin, but showed increased rates of hemoglobin/hematocrit drop (2.8% vs. 2.3%, $p=0.019$) and transfusions (1.7% vs. 1.3%, $p=0.044$), compared to warfarin. The frequency of abnormal laboratory values of liver function was balanced between the treatment groups. Rivaroxaban had similar rates of discontinuation due to adverse events compared to warfarin, and did not require routine laboratory coagulation monitoring.

"Given the prevalence and morbidity associated with atrial fibrillation, and the well-known difficulties with warfarin use, it is exciting to have an alternative which was documented in this study to be effective with no increase in significant bleeding," said Robert M. Califf, M.D., study co-chairman and Vice Chancellor for Clinical Research from Duke University.

With 14,264 randomized patients, ROCKET AF is the largest double-blind study completed to date for the prevention of stroke in patients with AF. The study compared oral, once-daily rivaroxaban (20 mg, or 15 mg in patients with moderate renal insufficiency) to dose-adjusted warfarin.

"Results from the ROCKET AF study suggest that rivaroxaban has the potential to offer protection for the millions of Americans living with atrial fibrillation who carry the risk of suffering a stroke, which is often devastating and disabling," said Peter M. DiBattiste, M.D., Vice President of Cardiovascular Development at Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

This is the seventh consecutive Phase 3 trial in the ongoing rivaroxaban global development program that has demonstrated either non-inferiority or superiority to standard of care.⁷⁻¹³

About Atrial Fibrillation

AF is the most common sustained cardiac rhythm disorder and affects more than 2.3 million people in the U.S.¹⁴ In patients with AF, the heart's irregular heartbeat makes them vulnerable to the formation of a blood clot in the atria, which can travel to the brain, potentially resulting in a stroke. Strokes can lead to physical and behavioral impairments, or even death. People living with AF are at a five-fold increased risk for stroke compared with the general population, and almost one third will suffer from a stroke in their lifetime.^{15,16}

About ROCKET AF

ROCKET AF (Rivaroxaban Once daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation) was a prospective, randomized, double-blind, double-dummy parallel group

outcomes study comparing once-daily rivaroxaban (20 mg, or 15 mg for patients with moderate renal impairment) with dose-adjusted warfarin in 14,264 patients with non-valvular atrial fibrillation who are at risk for stroke and non-CNS systemic embolism.

This was an event-driven trial, which ended when the pre-specified number of efficacy events was accumulated. The primary objective of ROCKET AF was to demonstrate the efficacy of once-daily rivaroxaban as non-inferior to dose-adjusted warfarin in the prevention of stroke and non-CNS systemic embolism in patients with non-valvular AF. The patients with AF evaluated in ROCKET AF typify those who are treated today by physicians with an anticoagulant to help reduce the risk of stroke.

About Rivaroxaban

Rivaroxaban is a novel oral anticoagulant being evaluated for the prevention and treatment of a broad range of disorders in which blood clotting plays a major role. In clinical studies, the compound has shown no requirement for routine laboratory coagulation monitoring, and limited risk for food and drug interactions. The extensive program of clinical trials evaluating rivaroxaban makes rivaroxaban the most studied oral, direct Factor Xa inhibitor in the world today. By the time of its completion, more than 65,000 patients will have participated in the rivaroxaban clinical development program. Rivaroxaban is being developed jointly by Johnson & Johnson Pharmaceutical Research & Development, L.L.C., which is part of the Johnson & Johnson family of companies, and Bayer HealthCare AG.

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(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from J&JPRD and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2010. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither J&JPRD nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

Resources for Media:

Additional information on rivaroxaban and AF, including backgrounder documents and high-resolution graphics, may be accessed at <http://multivu.prnewswire.com/mnr/johnsonandjohnson/46850/> and on the J&JPRD website: <http://www.jnjpharmarnd.com/jnjpharmarnd/rivaroxaban.html>

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2. On treatment is the period between the date of the first double-blind study medication to the date of the last double-blind study medication administration plus 2 days.
3. All percentages are events per 100 patient years, unless otherwise noted.
4. The ITT population includes all patients randomized into the trial - regardless of early discontinuation of the study medication - and followed until site notification (site notification is the notification to the site that the required primary efficacy endpoint events have been reached).
5. Major bleeding was defined as a fall in hemoglobin of 2 g/dL or more, a transfusion of two or more units of packed red blood cells or whole blood; a critical site; or a fatal outcome.
6. Non-major clinically relevant bleeding was defined as overt bleeding not meeting the criteria for major bleeding but associated with medical intervention, unscheduled contact with a physician, (temporary) cessation of study treatment, or associated with discomfort for the subject. Examples of non-major clinically relevant bleeding include nosebleed, bleeding gums, blood in the urine, and certain hematomas.
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