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Bayer ROCKET AF Study to be Reviewed by FDA

A Cardiovascular and Renal Drugs Advisory Committee meeting has been conducted, to review the New Drug Application in the USA for rivaroxaban in the prevention of stroke and non-CNS systemic embolism in patients with atrial fibrillation.

As outlined in the submission package that Bayer's development partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C (J&JPRD), provided to the FDA in advance of the Advisory Committee hearing, the companies are confident that the results of the ROCKET AF study properly demonstrate a favorable benefit risk balance for rivaroxaban compared to warfarin, reducing stroke and non-CNS systemic embolism, with low and comparable bleeding rates.

According to the FDA reviewers' assessment, excess bleeding did not occur with rivaroxaban in ROCKET, and there are no other safety concerns that preclude approval. In ROCKET AF, rivaroxaban was associated with significantly fewer of the most concerning bleeds, including intracranial hemorrhages, critical organ bleeds, and bleeding related deaths compared to warfarin.

Importantly, all-cause mortality trended in favor of rivaroxaban and the results were achieved in a unique patient population with a higher risk for recurrent thromboembolic events with a rigorous double-blind methodology. The increase in events observed following discontinuation of study drug in the rivaroxaban arm was considered likely due to the double blind design of the ROCKET AF study, and not to the drug itself.

"We are looking forward to an open and productive discussion during the FDA Advisory Committee Meeting and are confident in the results of ROCKET AF," said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer.

The Advisory Committee will consider the Sponsors' presentation, the FDA presentation, and the questions posed by the FDA, and their subsequent recommendation will be assessed by the FDA in its review of the New Drug Application for rivaroxaban. A decision by the FDA is expected in early November 2011.

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