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Singapore: US Food and Drug Administration has affirmed Boehringer Ingelheim's Pradaxa 150mg superior in reducing ischemic and hemorrhagic strokes relative to warfarin. This positive change is the result of the pivotal RE-LY trial conducted in 18,000 patients with non-valvular atrial fibrillation, which demonstrated unequivocally the superior benefits offered by Pradaxa, in terms of effective prevention of stroke.

"Ischaemic strokes account for up to 92 percent of strokes suffered by patients with atrial fibrillation, often leading to severe debilitation and poor prognosis," said Dr Hans-Christoph Diener, professor and chairman, Department of Neurology, University Duisburg-Essen, Germany. "For patients with atrial fibrillation, reducing the risk of stroke, especially ischaemic stroke, is the primary goal of anticoagulation treatment. It is important for both physicians and patients to have a treatment option that offers this decisive clinical benefit over warfarin when considering long term prevention from stroke."

Pradaxa 150mg is the only novel oral anticoagulant that has shown a significant reduction of both ischaemic and haemorrhagic strokes in patients with non-valvular atrial fibrillation when compared to warfarin in a major study.

"We welcome this update to the US prescribing information for Pradaxa, which clearly demonstrates the unique benefit offered by this novel treatment to patients and physicians worldwide," said Professor Klaus Dugi, corporate senior vice president-medicine, Boehringer Ingelheim. "By significantly reducing both ischaemic and haemorrhagic strokes, and at the same time providing significant reductions in intracranial bleeding, Pradaxa 150mg twice daily has the potential to protect patients from catastrophic events better than warfarin."