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Dabigatran etexilate is highly cost-effective for stroke prevention in Atrial Fibrillation (AF) especially in “real-world” clinical practice

Burlington, Ontario, March 22, 2011 – A new health economic analysis, published today online in *Thrombosis and Haemostasis*, suggested that Boehringer Ingelheim’s novel oral direct thrombin inhibitor dabigatran etexilate is cost-effective compared to current treatment options, particularly in “real-world” clinical practice.^{1,2}

The cost-effectiveness of dabigatran etexilate was driven by superior prevention of stroke and systemic embolism alongside a reduction in devastating intracranial bleeding compared to well-controlled warfarin, in patients with AF.²

In the “real-world” clinical practice setting, dabigatran etexilate was shown to be particularly cost-effective compared to current care. The “real-world” prescribing scenario reflects stroke prophylaxis in warfarin-eligible Canadian patients with AF as observed in actual clinical practice^{3,4} meaning patients could be receiving prophylaxis with warfarin, aspirin, or no treatment at all.

Dr. Stuart Connolly, principal investigator of the RE-LY® study, Director of Cardiology at the Population Health Institute, McMaster University, Hamilton, Ontario, and co-author of the economic evaluation commented, “We want to do the best for patients and dabigatran is the medically preferred treatment for stroke prevention. From the analyses reported today, we now know that it is cost-effective too - good value for our scarce healthcare budget.”

Typically healthcare decision makers assess whether new therapies represent good value for money by applying a threshold for additional health benefits (lower considered to be better value). In Canada, a threshold of \$30,000 per quality adjusted life year (QALY)-gained is considered acceptable while being conservative.²

The results of the health economic analysis showed that the incremental cost-effectiveness ratio (ICER) of dabigatran etexilate was \$10,440 / QALY versus “trial-like” warfarin and \$3,962 / QALY versus “real-world” warfarin, aspirin or no treatment.² This demonstrates that dabigatran etexilate is a cost-effective alternative to current care for the prevention of stroke among Canadian patients with AF.

AF is a leading cause of stroke⁵ and is associated with higher mortality and costlier hospital stays than stroke in patients without AF.⁶⁻⁸ Additionally, AF is associated with an increased risk of

systemic embolism which may result in major damage to limbs and organs (e.g. embolism [blood clot] in an artery).⁹

About the Study

This economic study modeled AF patients at risk of stroke who are eligible for anticoagulation treatment while tracking clinical events (primary and recurrent ischemic strokes, systemic embolism, transient ischemic attack [mini strokes], haemorrhage [bleeds], acute MI [heart attack] and death) and resulting functional disability. This analysis uses the results from the RE-LY® trial. Dabigatran etexilate was dosed using the approved Canadian dosing regimen: 150mg bid for patients <80 years and 110 mg bid for patients ≥ 80 years.²

About AF and stroke

Atrial fibrillation is an irregular heart rhythm known as arrhythmia that can cause the heart to beat very fast. While AF is rare in people under 40, its prevalence increases with age.¹⁰

Atrial fibrillation affects up to 250,000 Canadians,¹⁰ and is a serious yet common heart condition that can lead to severe and debilitating strokes. Canadians with AF are at least five times more at risk of having a stroke and are twice as likely to die from one.¹⁰ In Canada, stroke is a leading cause of adult disability and the third leading cause of death with up to 15 per cent of strokes being caused by AF.¹⁰

After the age of 55, the incidence of AF doubles with each decade of life.¹⁰ Other risk factors include heart disease, high blood pressure and diabetes. After age 60, one-third of all strokes are caused by AF.¹⁰

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Founded in 1885, the family-owned company is committed to researching and developing novel products of high therapeutic value for human and veterinary medicine. In 2009, Boehringer Ingelheim posted net sales of 12.7 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

The Canadian headquarters of Boehringer Ingelheim was established in 1972 and the Research and Development Centre located in Laval, Québec, Canada since 1988. Boehringer Ingelheim (Canada) Ltd. is home to more than 700 employees including 160 scientists across the country.

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