



Media contact: Azwar Kamarudin

P: 603-2281 6000

E: [Azwar.kamarudin@pfizer.com](mailto:Azwar.kamarudin@pfizer.com)

## **ELIQUIS® (apixaban) Approved In Malaysia for Prevention of Stroke and Venous Thromboembolism (VTE)**

- *ELIQUIS® is proven to show superior risk reductions versus warfarin in the three important outcomes: stroke, major bleeding and all-cause death*
- *ELIQUIS® has received approval in Malaysia for preventing strokes and VTE events*

**Kuala Lumpur, January 11, 2014** – Celebrating 50 years of making Malaysia a healthier country, Pfizer Malaysia has kicked off the year with the launch of the much-anticipated ELIQUIS®, an oral anticoagulant drug that has been approved for:

- *Prevention of venous thrombo embolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.*
- *Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).*

ELIQUIS® is an oral direct Factor Xa inhibitor, which is part of a novel therapeutic class, has demonstrated superior risk reduction versus warfarin in the three important outcomes of stroke and systemic embolism, major bleeding and all-cause mortality<sup>1</sup>.

### **AF-Related Strokes**

AF is caused when the two upper chambers of the heart (atria) beat rapidly and unpredictably, producing an irregular heartbeat. AF raises stroke risk because it allows blood to pool in the heart. When blood pools, it tends to form clots which can then be carried to the brain, causing a stroke. Long-term untreated AF can also weaken the heart, leading to heart failure. Atrial fibrillation symptoms include heart palpitations, shortness of breath and weakness.



The prevalence of AF is high in both community- and hospital-based studies in the Far East and South East Asia. Hypertension is the most common risk factor, but coronary heart disease and diabetes mellitus are other important co-morbidities in these countries. The prevalence of hypertension in Malaysia is 42.6% in adults above age of 30<sup>2</sup>.

“Hypertension in most patients is not well controlled and hypertension is responsible for more AF-related stroke in the population than any other risk factors. Based on the data collected by National Stroke Association of Malaysia (NASAM), stroke is the third largest cause of death and the single most common cause of severe disability in Malaysia. Stroke is estimated to hit six Malaysians every hour<sup>3</sup> and an average of 40,000 people in a year. With proper management, the risk of AF-related strokes can be reduced,” said Datuk Dr Razali Omar, a local Consultant Cardiologist and Electro Physiologist.

### **VTE: A Growing Concern**

Meanwhile, venous thromboembolism events are a growing major international health problem with millions of cases reported every year worldwide<sup>4,5</sup> and can be debilitating and potentially life-threatening.<sup>6</sup> Thrombosis occurs when a clot forms inside a blood vessel, obstructing the flow of blood with potentially serious and life threatening consequences. There are two types of VTE: deep vein thrombosis (DVT) where a blood clot forms in a vein deep in the body; and pulmonary embolism (PE) where a blood clot in a deep vein breaks off and travels to the artery in the lungs to block blood flow. Patients who undergo elective total knee or hip replacement surgery face a more than 10-fold greater risk of developing VTE.<sup>7</sup> Without preventive treatment, the approximate risk for this group of patients to develop deep vein thrombosis ranges from 40% to 60%.<sup>8</sup>

### **Unmet needs for safe and efficient treatment**

To reduce the risk of stroke and VTEs, healthcare providers can prescribe blood thinning medications, which can greatly reduce stroke risk if taken properly. While most AF-related strokes and VTEs could be prevented with blood thinners, up to two-thirds of AF patients who had strokes are not prescribed these medications and up to 91% of surgeons in Malaysia had



considered putting their patients on anticoagulant treatments.<sup>9</sup> Indeed, oral anticoagulation use ranges only between 0.5%–28% in Malaysia, Singapore, and China. In Malaysia, for example, the rate of warfarin usage was 20%. The proportion of patients receiving antiplatelet therapy was 18%–58%, although there was significant variability. Of concern, 22%–47% patients with AF did not receive any antithrombotic drugs.<sup>10</sup> Understandably, anticoagulant treatments are still not widely used either due to unsuitability of patients (who higher risks for bleeding) or the cumbersome monitoring infrastructure not available or accessible.

With the launch of the much-anticipated ELIQUIS®, an oral direct Factor Xa inhibitor, doctors and patients can welcome another medicine in the area of prevention of VTE, systemic embolism and stroke. “There remains a critical public health need for improved treatment options to prevent stroke incidences and reduce risk of serious complications of VTE. The approval of [ELIQUIS® apixaban](#) for these double threats is a welcomed innovation in oral anticoagulant treatment. The clinical trials have given the healthcare providers much to look forward to in helping our patients treat and reduce stroke, major bleeding and death in patients with VTE,” said Dr. Renato Lopes, Associate Professor of Medicine, Cardiology, Duke Clinical Research Institute, Duke University, USA.

“It is through Pfizer’s pursuit in scientific innovation and our relentless commitment in bringing innovative and meaningful medicines and treatments to our healthcare providers and patients that we are able to make a difference in the evolution of stroke and VTE management. The launch of ELIQUIS® is Pfizer’s continuous effort to address the unmet need for improved treatment options for cardiovascular patients. With our combined cardiovascular leadership and expertise, we are confident that ELIQUIS® will transform the standard of care in stroke and VTE prevention in Malaysia,” said [Azwar Kamarudin, Director of Corporate Affairs & Market Access, Pfizer Malaysia.](#) ~~[Angel Choi, Country Manager of Pfizer Malaysia.](#)~~

ELIQUIS® is supported by the pivotal Phase 3 trials ARISTOTLE<sup>11</sup> and AVERROES<sup>12</sup>, which evaluated approximately 24,000 patients with non-valvular atrial fibrillation (NVAF) in the largest completed clinical trial program conducted to date in this patient population. The ELIQUIS® clinical program ~~is the only~~ Phase 3 clinical program among the new oral anticoagulants to



evaluate the safety and efficacy of ELIQUIS® versus aspirin in patients who were unsuitable for vitamin K antagonist (VKA) therapy.

ELIQUIS® 2.5mg and 5 mg is indicated as a twice-daily oral medication for prevention of stroke and systemic embolism in adult patients with NVAf with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age  $\geq$  75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class  $\geq$  II). ELIQUIS® does not require International Normalized Ratio (INR) monitoring and there are no known dietary restrictions.

ELIQUIS® is ~~the only~~ oral anticoagulant with a 12-24 hour post-surgical initiation window. This allows physicians to monitor the patient's recovery, evaluate the potential benefits of earlier anticoagulation for VTE and identify risks of post-surgical bleeding before deciding on the time of administration of the first dose of ELIQUIS®. The post-surgical initiation window and subsequent twice-daily dosing (2.5 mg) also allows time for the patient's natural healing process to begin.<sup>13</sup>

ELIQUIS® requires no routine platelet or liver monitoring, and requires no dose adjustment in indicated patients. In patients undergoing hip replacement surgery, the recommended duration of treatment is 32 to 38 days. In patients undergoing knee replacement surgery, the recommended duration of treatment is 10 to 14 days.<sup>14</sup>

###

#### **About Stroke**

A stroke is a condition in which the brain cells suddenly die because of a lack of oxygen. A stroke can be caused by an obstruction in the blood flow, or the rupture of an artery that feeds the brain. The patient may suddenly lose the ability to speak, there may be memory problems, or one side of the body can become paralyzed.

#### **About Venous Thromboembolism**

VTE encompasses two serious conditions: Deep Vein Thrombosis (DVT), a blood clot in a vein, usually in the leg that partially or totally blocks the flow of blood; and Pulmonary Embolism (PE), a blood clot blocking one or more vessels in the lungs.<sup>15</sup> DVT causes multiple symptoms including pain, swelling and redness and, more importantly, can progress to PE, which carries the risk of sudden death.



## About the ELIQUIS®

ELIQUIS® is an oral direct Factor Xa inhibitor, part of a new therapeutic class. By inhibiting Factor Xa, a key blood clotting protein, ELIQUIS® prevents thrombin generation and blood clot formation.

## Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading Biopharmaceutical Company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

---

<sup>1</sup> Christopher B. Granger et al. Apixaban versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2011; 365:981-992 September 15, 2011 DOI: 10.1056/NEJMoa1107039

<sup>2</sup> Wong J.S. et al Prevalence of asymptomatic atrial fibrillation in Malaysian patients with hypertension. [Med J Malaysia](#). 2013 Apr;68(2):141-3.

<sup>3</sup>M. Krishnamoorthy. Killer Stroke: 6 Malaysians Hit Every Hour.  
<http://www.thestar.com.my/story.aspx?file=%2F2007%2F4%2F24%2Fnation%2F17524877>

<sup>4</sup> Cohen AT, Agnelli G, Anderson FA et al. For the VTE Impact Assessment Group in Europe (VITAE). Venous thromboembolism (VTE) in Europe. The number of VTE events and associated morbidity and mortality. *Thromb Haemost*. 2007; 98(4):756-64.

<sup>5</sup> Anderson FA Jr, Wheeler HB, Goldberg RJ et al. A population-based perspective of the hospital incidence and case-fatality rates of deep vein thrombosis and pulmonary embolism. The Worcester DVT Study. *Arch Intern Med*. 1991; 151(5):933-8.

<sup>6</sup> White RH. The epidemiology of venous thromboembolism. *Circulation* 2003; 107; 1-4-1-8.

<sup>7</sup> Anderson FA Jr, Spencer FA. Risk factors for venous thromboembolism. *Circulation* 2003; 107(23)(suppl 1):1-9-1-16.

<sup>8</sup> Geerts WH, Bergqvist D, Pineo GF et al. Prevention of Venous Thromboembolism. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest* 2008; 133:381S-453S.

<sup>9</sup> ZF Zairul-Nizam, YA Gul. Malaysian orthopaedic surgeons' approach to venous thromboembolic disease prophylaxis: attitudes and practice. *Journal of Orthopaedic Surgery* 2003; 11(2): 178-183 <http://www.josonline.org/PDF/v11i2p178.pdf>

<sup>10</sup> Yutao Guo, Gregory Y.H.Lip, and Stavros Apostolakis. The Unmet Need of Stroke Prevention in Atrial Fibrillation in the Far East and South East Asia. *Malays J Med Sci*. 2012 Jul-Sep; 19(3):1-7

---

<sup>11</sup> Christopher B. Granger et al. Apixaban versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med 2011; 365:981-992 September 15, 2011 DOI: 10.1056/NEJMoa1107039

<sup>12</sup> Stuart J. Connolly et al. Apixaban in Patients with Atrial Fibrillation. N Engl J Med 2011; 364:806-817 March 3, 2011 DOI: 10.1056/NEJMoa100743

<sup>13</sup> Schultz GS, Ladwig G, Wysocki A. Extracellular matrix: review of its roles in acute and chronic wounds. World Wide Wounds. Available at: <http://www.worldwidewounds.com/2005/august/Schultz/Extrace-Matric-Acute-Chronic-Wounds.html>

<sup>14</sup> ELIQUIS™ (apixaban) Summary of Product Characteristics. March 2011.

<sup>15</sup> Cohen AT, Agnelli G, Anderson FA et al. for the VTE Impact Assessment Group in Europe (VITAE). Venous thromboembolism (VTE) in Europe. The number of VTE events and associated morbidity and mortality. Thromb Haemost. 2007;98(4):756-64.