Pfizer Logo

Bristol-Myers Squibb and Pfizer Announce Enrollment of First Patient in Phase IV EMANATE Trial to Assess Effectiveness and Safety of Eliquis® (apixaban) in Patients with NVAF Undergoing Cardioversion

Thursday, July 17, 2014 - 04:06am

Bristol-Myers Squibb Company (NYSE:BMY) and Pfizer Inc. (NYSE:PFE) today announced that the first patient has been enrolled into a Phase IV clinical trial called EMANATE (***E****liquis* evaluated in acute cardioversion co**M**pared to usu**A**l treatme**N**ts for **A**n**T**icoagulation in subj**E**cts with NVAF) assessing the effectiveness and safety of *Eliquis* in patients with nonvalvular atrial fibrillation (NVAF) undergoing cardioversion. *Eliquis* is currently approved to reduce the risk of stroke and systemic embolism in patients with NVAF. Cardioversion (administered through electric shock to the chest or with medication) is a commonly used, effective method of converting atrial fibrillation to a normal rhythm, allowing the heart to pump more effectively. Traditionally, anticoagulation is administered for a minimum of three weeks prior to cardioversion and for four weeks afterward. In some patients, early cardioversion can be performed on the same day or within days of new-onset NVAF, usually after imaging, to confirm the absence of a pre-existing thrombus in the heart, which could be dislodged during the cardioversion procedure and cause a stroke.

EMANATE, a randomized, open-label clinical trial, will assess the effectiveness and safety of *Eliquis* compared with usual care (parenteral heparin and/or oral anticoagulation with a vitamin K antagonist) initiated in patients with NVAF expected to undergo cardioversion after short-term anticoagulation, in a clinical practice setting. In NVAF patients presenting at least 48 hours after the onset of NVAF, early cardioversion will be performed after excluding a thrombus by imaging, on the same day or within a few days. In NVAF patients presenting within 48 hours of the onset of NVAF, cardioversion will be performed promptly without prior imaging. In all patients, *Eliquis* or usual care will be initiated prior to cardioversion and continued for up to 30 days post-cardioversion.

The EMANATE trial is anticipated to enroll 1,500 eligible patients from the U.S., Canada, Europe and Asia. Patients will be randomized 1:1 to *Eliquis* or usual care, to be administered for up to 30 days following early cardioversion or 90 days post randomization if cardioversion is not performed within this timeframe. The primary efficacy endpoints are the occurrence of acute stroke, systemic embolism and all-cause death. Primary safety endpoints are major bleeding and clinically relevant non-major bleeding.

“We are pleased to enroll our first patient in the Phase IV EMANATE study,” said Jack Lawrence, MD, vice president, Cardiovascular Global Clinical Research and development lead, *Eliquis*, Bristol-Myers Squibb. “This Phase IV trial will provide important data that will inform the use of*Eliquis* in patients with NVAF undergoing cardioversion.”

“*Eliquis* is approved to reduce the risk of stroke and systemic embolism in patients with NVAF in a number of countries around the world, including in the U.S., European Union and Japan,” said Steve Romano, senior vice president, head of Medicines Development Group for Global Innovative Pharmaceuticals, Pfizer Inc. “The initiation of the Phase IV EMANATE study reinforces the long-term commitment of Bristol-Myers Squibb and Pfizer to understanding and improving health in patients with NVAF.”

INDICATION

ELIQUIS is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

ELIQUIS is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

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IMPORTANT SAFETY INFORMATION

**WARNINGS: (A) DISCONTINUING ELIQUIS IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLAT
CONTINUOUS ANTICOAGULATION INCREASES RISK OF STROKE, (B) SPINAL/EPIDURAL HEMATO**

**(A) Discontinuing ELIQUIS places patients at an increased risk of thrombotic events. An increased rate of stroke
of ELIQUIS in clinical trials in patients with nonvalvular atrial fibrillation. If anticoagulation with ELIQUIS mu
pathological bleeding, coverage with another anticoagulant should be strongly considered.**

**(B) When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulate
low molecular weight heparins, heparinoids, or Factor Xa inhibitors for prevention of thromboembolic complicat
or spinal hematoma which can result in long-term or permanent paralysis.**

**The risk of these events may be increased by the use of indwelling epidural catheters for administration of analge
affecting hemostasis such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet aggregation inhibitors, or c
appears to be increased by traumatic or repeated epidural or spinal puncture.**

**Monitor patients for signs and symptoms of neurologic impairment. If neurologic compromise is noted, urgent tr
potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for t**

CONTRAINDICATIONS

- Active pathological bleeding
- Severe hypersensitivity reaction to ELIQUIS (apixaban) (e.g., anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- **Increased Risk of Stroke with Discontinuation of ELIQUIS in Patients with Nonvalvular Atrial Fibrillation:** Discontinuing ELIQUIS in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in patients with nonvalvular atrial fibrillation. If ELIQUIS must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant.
- **Bleeding Risk:** ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal bleeding. Concomitant use of drugs affecting hemostasis increases the risk of bleeding including aspirin and other anti-platelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs. Patients should be made aware of signs or symptoms of blood loss and instructed to immediately report to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
- There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). A specific antidote for ELIQUIS is not available. Hemodialysis does not appear to have a substantial impact on apixaban exposure. Protamine sulfate and vitamin K would not be expected to affect the anticoagulant activity of apixaban. There is no experience with antifibrinolytic agents (tranexamic acid, aminocaproic acid) in individuals receiving apixaban. There is neither scientific rationale for reversal nor experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving apixaban. Use of procoagulant reversal agents such as prothrombin complex concentrate, activated prothrombin complex concentrate, or recombinant factor VIIa may be considered but has not been evaluated in clinical studies. Activated charcoal reduces absorption of apixaban thereby lowering apixaban plasma concentrations.

- **Prosthetic Heart Valves:** The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients.

ADVERSE REACTIONS

The most common and most serious adverse reactions reported with ELIQUIS (apixaban) were related to bleeding.

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be noncritical in location and easily controlled. Bridging anticoagulation during the 24 to 48 hours after stopping ELIQUIS and prior to the intervention is not generally required. ELIQUIS should be restarted after the surgical or other procedures as soon as adequate hemostasis has been established.

DRUG INTERACTIONS

- **Strong Dual Inhibitors of CYP3A4 and P-gp:** Inhibitors of CYP3A4 and P-gp increase exposure to apixaban and increase the risk of bleeding. For patients receiving 5 mg twice daily, the dose of ELIQUIS should be decreased when it is coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin). In patients already taking ELIQUIS at a dose of 2.5 mg twice daily, avoid coadministration with strong dual inhibitors of CYP3A4 and P-gp.
- **Strong Dual Inducers of CYP3A4 and P-gp:** Avoid concomitant use of ELIQUIS with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John’s wort) because such drugs will decrease exposure to apixaban and increase the risk of stroke.
- **Anticoagulants and Antiplatelet Agents:** Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

PREGNANCY CATEGORY B

There are no adequate and well-controlled studies of ELIQUIS in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. ELIQUIS should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.

Please see full Prescribing Information, including BOXED WARNINGS and Medication Guide, available at www.bms.com.

About Nonvalvular Atrial Fibrillation (NVAF)

Atrial fibrillation is the most common type of irregular heartbeat. It is estimated that more than 5.8 million Americans and six million individuals in Europe have atrial fibrillation. One of the most serious medical concerns for individuals with atrial fibrillation is the increased risk of stroke, which is five times higher in people with atrial fibrillation than in people without atrial fibrillation. In North America and Europe, it is estimated that 98 percent of patients with atrial fibrillation have NVAF. NVAF is a type of atrial fibrillation that is not due to rheumatic mitral heart valve disease, a prosthetic heart valve, or a repairing of the heart’s mitral valve.

About *Eliquis*®

Eliquis (apixaban) is an oral selective Factor Xa inhibitor. By inhibiting Factor Xa, a key blood clotting protein, *Eliquis* decreases thrombin generation and blood clot formation. *Eliquis* is approved to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation in the United States, European Union, Japan and a number of other countries around the world. *Eliquis* is approved for the prophylaxis of deep vein thrombosis (DVT) which can lead to pulmonary embolism (PE) in adult patients who have undergone elective hip or knee replacement surgery in the United States, European Union and a number of other countries around the world. *Eliquis* is not approved for this indication in Japan.

About the Bristol-Myers Squibb/Pfizer Collaboration

In 2007, Pfizer and Bristol-Myers Squibb entered into a worldwide collaboration to develop and commercialize apixaban, an oral anticoagulant discovered by Bristol-Myers Squibb. This global alliance combines Bristol-Myers Squibb's long-standing strengths in cardiovascular drug development and commercialization with Pfizer’s global scale and expertise in this field.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit http://www.bms.com.

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

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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. To learn more, please visit us at www.pfizer.com.

Bristol-Myers Squibb Forward-Looking Statement

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