Pfizer Logo

FDA Accepts ELIQUIS® (apixaban) New Drug Application for Review for the Prevention of Stroke and Systemic Embolism in Patients with Atrial Fibrillation

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(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for ELIQUIS® (apixaban), an investigational compound for the prevention of stroke and systemic embolism in patients with atrial fibrillation. The FDA accepted the filing and assigned a priority-review designation. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is March 28, 2012.

As previously disclosed, an application for ELIQUIS for stroke prevention in atrial fibrillation has been validated for review by the European Medicines Agency.

The submissions were based on the results of the ARISTOTLE and AVERROES studies, two Phase 3 trials that evaluated the efficacy and safety of ELIQUIS for the prevention of stroke or systemic embolism in patients with atrial fibrillation. These two trials, which included approximately 24,000 patients, comprise the largest completed clinical development program for stroke prevention in atrial fibrillation among novel oral anticoagulants, and included patients eligible for anticoagulant therapy based on current treatment guidelines, as well as patients expected or demonstrated to be unsuitable for vitamin K antagonist (VKA) therapy.

About Atrial Fibrillation

Atrial fibrillation is the most common sustained cardiac arrhythmia, or irregular heart beat. It is estimated that more than 5 million Americans and 6 million individuals in Europe have atrial fibrillation. The lifetime risk of atrial fibrillation is estimated to be approximately one in four for individuals 40 years of age or older. The most serious medical issue for individuals with atrial fibrillation is the increased risk of stroke, which is five times higher in people with atrial fibrillation than those without atrial fibrillation. In fact, 15 percent of all strokes in the U.S. are attributable to atrial fibrillation. Additionally, strokes due to atrial fibrillation are more burdensome than strokes due to other causes. Atrial fibrillation-related strokes are more severe than other strokes with an associated 30-day mortality of 24 percent and a 50 percent likelihood of death within one year.

About ELIQUIS

ELIQUIS is the approved trade name for apixaban in Europe and the proposed trade name in the U.S. ELIQUIS is not approved for the prevention of stroke and systemic embolism in patients with atrial fibrillation. In May 2011, Bristol-Myers Squibb and Pfizer announced the first regulatory approval for ELIQUIS in the 27 countries of the European Union (EU) for the prevention of venous thromboembolic events (VTE) in adult patients who

have undergone elective hip or knee replacement surgery.

ELIQUIS is being investigated within the EXPANSE Clinical Trials Program, which is projected to include nearly 60,000 patients worldwide across multiple indications and patient populations and includes a total of nine completed or ongoing, randomized, double-blind Phase 3 trials.

About the Bristol-Myers Squibb/Pfizer Collaboration

In 2007, Pfizer and Bristol-Myers Squibb entered into a worldwide collaboration to develop and commercialize ELIQUIS, an investigational 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 or follow us on Twitter at http://twitter.com/bmsnews.

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.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there is no guarantee that the FDA will approve the NDA described in this release. There is also no guarantee that, if approved in this indication, apixaban will become a commercially successful product. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2010, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

PFIZER DISCLOSURE NOTICE:

The information contained in this release is as of November 29, 2011. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about various potential indications for ELIQUIS (apixaban), including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that have been or may be filed for any such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

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