ELIQUIS® (apixaban) Approved In Japan For The Prevention Of Stroke And Systemic Embolism In Patients With Nonvalvular Atrial Fibrillation

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(BUSINESS WIRE)--Bristol-Myers Squibb (NYSE: BMY) and Pfizer Inc. (NYSE: PFE) announced today that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved ELIQUIS® (apixaban) for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). ELIQUIS is a novel anticoagulant that has demonstrated risk reductions versus warfarin in three important outcomes of stroke, major bleeding and all-cause death. ELIQUIS is an oral direct Factor Xa inhibitor, part of a novel therapeutic class. This is the third approval for ELIQUIS for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, following approvals in the European Union and Canada.

“Today’s approval of ELIQUIS is the result of our shared vision with Pfizer to introduce a differentiated treatment option to reduce the burden of stroke in patients with nonvalvular atrial fibrillation,” said Charles Bancroft, executive vice president, Intercontinental Region and Japan, and chief financial officer, Bristol-Myers Squibb. “We are confident in the clinical profile of ELIQUIS and look forward to making this important medicine available to patients in Japan.”

“The approval in Japan marks the third regulatory approval for ELIQUIS within six weeks,” said John Young, president and managing director, Pfizer Primary Care Business Unit. “We are excited by this momentum and confident that our combined cardiovascular leadership and expertise with BMS will lead to a successful introduction of this important medicine to patients and physicians in Japan.”

The approval of ELIQUIS in Japan is supported by the pivotal Phase 3 trial, ARISTOTLE, which evaluated the safety and efficacy of ELIQUIS versus warfarin in 18,201 patients with NVAF, including 336 patients from Japan. Additionally, the safety and efficacy of ELIQUIS in Japanese patients were evaluated in a subanalysis of the ARISTOTLE study, which demonstrated results consistent with the overall study. The application for ELIQUIS for the prevention of ischemic stroke and systemic embolism was submitted in Japan on December 21, 2011.

The companies continue to progress the ELIQUIS application for stroke prevention in atrial fibrillation in other markets. On September 26, 2012, The U.S. Food and Drug Administration (FDA) acknowledged receipt of the ELIQUIS New Drug Application (NDA) resubmission to reduce the risk of stroke and systemic embolism in adult patients with NVAF. The FDA has deemed the resubmission a complete response to its June 22, 2012 Complete Response Letter (CRL) that requested additional information on data management and verification from the ARISTOTLE trial. The FDA Prescription Drug User Fee Act (PDUFA) date is March 17, 2013.

About Atrial Fibrillation

Atrial fibrillation is the most common cardiac arrhythmia (irregular heart beat). The lifetime risk of developing atrial fibrillation is estimated to be approximately 25% for individuals 40 years of age or older. 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 those without atrial fibrillation. In fact, atrial fibrillation is responsible for approximately 20% of all strokes in Japan. Atrial fibrillation-related strokes are more severe than other strokes, with an associated 30-day mortality of 24% and a 50% likelihood of death within one year in patients who are not treated with an antithrombotic.

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. Bristol-Myers Squibb and Pfizer will be engaged in providing medical information with proper use of medicines.

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, 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 can be no guarantee that ELIQUIS will become a commercially successful product in Japan or that it will receive regulatory approval in the U.S. or other markets. 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, 2011, 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 December 26, 2012. 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 ELIQUIS (apixaban) that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, (i) the uncertainties regarding the commercial success of ELIQUIS in Japan for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) the companies' ability to address the comments in the complete response letter from the U.S. Food and Drug Administration (FDA) expeditiously and to the satisfaction of the FDA; (iii) decisions by the FDA and regulatory authorities in other jurisdictions regarding whether and when to approve drug applications that have been or may be filed for ELIQUIS for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of that indication; and (iv) 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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