Pfizer Logo

FDA Acknowledges Receipt of Resubmission of the ELIQUIS® (apixaban) New Drug Application to Reduce the Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation

Wednesday, September 26, 2012 - 07:31am

(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 acknowledged receipt of the New Drug Application (NDA) resubmission for ELIQUIS® (apixaban) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). The FDA assigned a new Prescription Drug User Fee Act (PDUFA) goal date of March 17, 2013. The FDA has deemed the resubmission a complete response to its June 22, 2012 Complete Response Letter that requested additional information on data management and verification from the ARISTOTLE trial.

The ELIQUIS NDA is based on the results of the ARISTOTLE and AVERROES studies. These clinical studies evaluated ELIQUIS in approximately 24,000 patients with NVAF, in the largest clinical trial program conducted to date in this patient population. The landmark ARISTOTLE trial compared apixaban to warfarin, the standard of care, in more than 18,000 NVAF patients, while AVERROES compared apixaban to aspirin in 5,598 NVAF patients who were unsuitable for vitamin K antagonist (VKA) therapy.

ARISTOTLE and AVERROES are part of an ongoing clinical development program for ELIQUIS, 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 III trials.

The companies continue to progress the ELIQUIS application for stroke prevention in atrial fibrillation in markets outside of the U.S., including the European Union and Japan, based on the ARISTOTLE and AVERROES studies. On September 21, 2012, Bristol-Myers Squibb and Pfizer Inc. announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending that ELIQUIS (apixaban) be granted approval for the prevention of stroke and systemic embolism in adult patients with NVAF and with one or more risk factors for stroke.

About Atrial Fibrillation

Atrial fibrillation is the most common cardiac arrhythmia (irregular heart beat). It is estimated that more than 5.8 million Americans and 6 million individuals in Europe have atrial fibrillation. The lifetime risk of developing atrial fibrillation is estimated to be approximately 25 percent 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, 15 percent of all strokes are attributable to atrial fibrillation in the U.S. 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 in patients who are not treated with an antithrombotic.

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 or systemic embolism in patients with atrial fibrillation in any country. In May 2011, Bristol-Myers Squibb and Pfizer announced the first regulatory approval for ELIQUIS in the 27 countries of the European Union plus Iceland and Norway for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.

ELIQUIS is also being investigated in Phase III trials for the treatment of VTE.

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. To learn more about our commitments, please visit us at www.pfizer.com.

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 apixaban will receive regulatory approvals for an indication in stroke prevention in patients with atrial fibrillation or that

any such approvals will be received within the time periods 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, 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 September 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 various potential indications for ELIQUIS (apixaban), including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, (i) the uncertainties inherent in research and development; (ii) the companies' ability to address the comments in the June 22, 2012 complete response letter (CRL) to the satisfaction of the Food and Drug Administration (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 such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such indications; 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.

Bristol-Myers Squibb Media: Laura Hortas, 609-252-4587, laura.hortas@bms.com Investors: John Elicker, 609-252-4611, john.elicker@bms.com or Pfizer Inc. Media: MacKay Jimeson, 212-733-2324, MacKay.Jimeson@pfizer.com Investors: Suzanne Harnett, 212-733-8009, Suzanne.Harnett@pfizer.com