

# Bristol-Myers Squibb and Pfizer Receive Complete Response Letter from U.S. Food and Drug Administration for ELIQUIS® (apixaban)

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[\(BUSINESS WIRE\)](#)--[Bristol-Myers Squibb Company](#) (NYSE: BMY) and [Pfizer](#) (NYSE: PFE) announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for ELIQUIS® (apixaban) for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

The CRL requests additional information on data management and verification from the ARISTOTLE trial. Bristol-Myers Squibb and Pfizer will work closely with the FDA on the appropriate next steps for the ELIQUIS application. The FDA has not requested that the companies complete any new studies. FDA and the companies are committed to working expeditiously to address the outstanding questions and move the application forward.

"There is a significant unmet need to reduce the risk of stroke in patients with atrial fibrillation," said Elliott Sigal, M.D., Ph.D., Executive Vice President and Chief Scientific Officer, Bristol-Myers Squibb. "We believe that the two large trials called ARISTOTLE and AVERROES have established the therapeutic profile for ELIQUIS and demonstrated a meaningful advance over the standard of care."

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. These studies evaluated ELIQUIS in approximately 24,000 patients with atrial fibrillation, including patients who are expected or demonstrated to be unsuitable for vitamin K antagonist (VKA) therapy. The companies are committed to 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 3 trials.

## 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 for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. In February 2012, the companies announced that the FDA had extended the action date for the ELIQUIS NDA for prevention of stroke and

systemic embolism in patients with atrial fibrillation by three months to June 28, 2012 based on a major amendment to the NDA.

In addition to stroke prevention in patients with atrial fibrillation and the prevention of VTE in patients who have undergone total hip or total knee replacement surgery, ELIQUIS is being investigated in Phase 3 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](http://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 approval for an indication in stroke prevention in patients with atrial fibrillation or that any such approval will be received within the time period 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 June 25, 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, the uncertainties inherent in research and development; the companies' ability to address the comments in the CRL expeditiously and to the satisfaction of the FDA; 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 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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