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ELIQUIS® (apixaban) Demonstrated Superiority In Reducing A Composite Of Recurrent Venous Thromboembolism And All-Cause Death Without Increasing The Rate Of Major Bleeding Versus Placebo During One Year Of Extended Treatment

Saturday, December 08, 2012 - 03:30am

New Phase 3 Results Published today in New England Journal of Medicine and Will Be Presented as a Late-Breaker at American Society for Hematology Annual Meeting

"Up to 10 percent of patients will experience a recurrent venous thromboembolism event after completing the currently recommended six-to-twelve-month treatment period, suggesting the need for additional prophylaxis,"

(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc. (NYSE: PFE) today announced the results of the Phase 3 AMPLIFY-EXT trial, which evaluated treatment with ELIQUIS® (apixaban) over a one-year period compared to placebo for the prevention of recurrent venous thromboembolism (VTE) in 2,486 patients who had already completed 6 to 12 months of anticoagulation treatment for VTE, including deep vein thrombosis (DVT) or pulmonary embolism (PE). In the trial, extended treatment with ELIQUIS 2.5 mg and 5 mg twice daily, demonstrated superiority versus placebo in the reduction of the composite endpoint of symptomatic, recurrent VTE and death from any cause (11.6% in the placebo group, compared with 3.8% and 4.2% in the ELIQUIS 2.5 mg and 5 mg groups, respectively, P<0.001), the primary efficacy outcome of the trial.

ELIQUIS also was superior to placebo for the predefined secondary efficacy outcome of recurrent VTE and VTE-related death (8.8% in the placebo group, compared with 1.7% in both the ELIQUIS 2.5 mg and 5 mg groups). Both of these endpoints, the primary and secondary efficacy outcomes, were statistically significant (p<0.001).

The rate of the primary safety outcome of major bleeding was comparable across treatment groups (0.2 % for ELIQUIS 2.5 mg; 0.1 % for ELIQUIS 5 mg and 0.5% for placebo). The rate of the composite of major bleeding and clinically relevant non-major bleeding for the 5 mg treatment group (4.3%) was higher versus the placebo group (2.7%), while the rate for the 2.5 mg treatment group (3.2%) was similar to the placebo group. The findings were published online today in *The New England Journal of Medicine* and announced at a press briefing during the 54th Annual Meeting of the American Society of Hematology (ASH).

“Up to 10 percent of patients will experience a recurrent venous thromboembolism event after completing the currently recommended six-to-twelve-month treatment period, suggesting the need for additional prophylaxis,”

said Dr. Giancarlo Agnelli, professor of internal medicine, University of Perugia, Italy; director of the Department of Internal and Cardiovascular Medicine and Stroke-Unit, University Hospital, Perugia, Italy; and lead investigator of the study. “In the AMPLIFY-EXT trial, which added an additional year of treatment, ELIQUIS reduced the composite risk of recurrent venous thromboembolism and total mortality without an increase in major bleeding versus placebo.”

About AMPLIFY-EXT

AMPLIFY-EXT (**A**pixaban after the initial **M**anagement of **P**u**L**monary embol**I**sm and deep vein thrombosis with **F**irst-line therap**Y**-**EXT**ended Treatment), a randomized, double-blind, multicenter trial, included 2,486 patients with prior VTE who had completed 6 to 12 months of anticoagulation treatment for DVT or PE and for whom there was clinical equipoise about the need for continued anticoagulation. Patients were randomized to receive either ELIQUIS 2.5 mg or 5 mg, or placebo twice daily for 12 months.

The primary efficacy outcome was the combined endpoint of symptomatic, recurrent VTE (nonfatal DVT or nonfatal PE) and death from any cause. Death was classified as VTE-related, cardiovascular-related, due to bleeding, or due to other causes. For the primary efficacy outcome, ELIQUIS demonstrated superiority versus placebo (11.6% in the placebo group, compared with 3.8% and 4.2% in the ELIQUIS 2.5 mg and 5 mg groups, respectively, $P<0.001$). For the primary efficacy analysis, as agreed with regulatory authorities, patients lost to follow-up were counted as having the primary outcome. For secondary analysis, such as VTE or VTE-related death and for the safety analyses, patients lost to follow-up were counted as not having an event.

ELIQUIS demonstrated superiority for the predefined secondary efficacy outcome of recurrent VTE and VTE-related death (8.8% in the placebo group, compared with 1.7% in both the ELIQUIS 2.5 mg and 5 mg groups). Both of these endpoints, the primary and secondary efficacy outcomes, were statistically significant ($p<0.001$). ELIQUIS demonstrated lower all-cause mortality (placebo group was 1.7%, compared with 0.8% and 0.5% in the ELIQUIS 2.5 mg and 5 mg groups, respectively), though the difference was not statistically significant.

The primary safety outcome was major bleeding. Major bleeding rates were low and ELIQUIS demonstrated comparable rates with placebo (0.5% in the placebo group, 0.2% in the ELIQUIS 2.5 mg group, and 0.1% in the ELIQUIS 5 mg group). Rates of composite major bleeding or clinically relevant non-major bleeding were 2.7% in the placebo group, 3.2% in the ELIQUIS 2.5 mg group, and 4.3% in the ELIQUIS 5 mg group.

In AMPLIFY-EXT, the rates of adverse events were similar across all treatment groups. The efficacy and bleeding outcomes were consistent across pre-specified subgroups.

About Venous Thromboembolism

Venous thromboembolism, or VTE, encompasses two serious conditions: deep vein thrombosis (DVT), a blood clot in a vein, usually in the leg, that partially or totally blocks the flow of blood; and pulmonary embolism (PE), a blood clot blocking one or more vessels in the lungs. VTE continues to be a major cause of morbidity and mortality, with approximately 900,000 patients in the U.S. and approximately 1 million patients in the EU diagnosed every year.

About ELIQUIS

ELIQUIS is an oral direct Factor Xa inhibitor, part of a new therapeutic class. By inhibiting Factor Xa, a key blood clotting protein, ELIQUIS prevents thrombin generation and blood clot formation. ELIQUIS is the approved trade name for apixaban in Europe and the proposed trade name in the U.S. 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. On November 20, 2012, Bristol-Myers Squibb and Pfizer announced the European Commission became the first regulatory authority globally to approve ELIQUIS for the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors. Bristol-Myers Squibb and Pfizer announced on December 6, 2012, that Health Canada approved ELIQUIS for the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF).

The companies continue to progress the ELIQUIS application for stroke prevention in atrial fibrillation based on the ARISTOTLE and AVERROES studies. 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.

In addition to the AMPLIFY-EXT trial, ELIQUIS is also being investigated in the AMPLIFY Phase 3 trial.

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 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 ELIQUIS *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 December 8, 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 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 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 (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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