# Data on ELIQUIS® (apixaban) for the Prevention of Stroke in Atrial Fibrillation To Be Presented At American College of Cardiology's 61st Annual Scientific Session

Wednesday, March 21, 2012 - 12:11am

--(<u>BUSINESS WIRE</u>)--<u>Bristol-Myers Squibb Company</u> (NYSE: BMY) and <u>Pfizer Inc.</u> (NYSE: PFE) today announced additional analyses from the ARISTOTLE and AVERROES clinical trials will be presented at the American College of Cardiology's 61<sup>st</sup> Annual Scientific Session, March 24-27, 2012, in Chicago. The two large Phase 3 clinical trials compared ELIQUIS<sup>®</sup> (apixaban), an investigational compound for the prevention of stroke or systemic embolism in patients with nonvalvular atrial fibrillation, with warfarin and aspirin, respectively.

Data analyses on ELIQUIS to be presented during the congress include:

Session Details Presentation Title Lead Author

Sunday, March 25, 2012

8:30 – 8:45 CDT Alpesh N. Amin, MD,

Total Medical Costs Avoided with Apixaban MBA, FACP,

ACC Oral Contributions versus Aspirin Treatment among Atrial

Fibrillation Patients Unable or Unwilling to University of

913. Insights and Innovations to Improve Take Warfarin, Based on the AVERROES Trial California, Irvine,

Cardiac Risk Results CA, U.S.

McCormick Place North, N229

Sunday, March 25, 2012

8:51 - 9:03 CDT

**ACC Oral Contributions** 

904. Management of the Patient with Atrial Fibrillation: Anticoagulation and Prevention of Stroke-- Joint Oral Arrhythmias Session of the Heart Rhythm Society and the American College of Cardiology Efficacy and Safety of Apixaban Compared with Warfarin According to CHADS<sub>2</sub> and HASBLED Risk Scores for Stroke Prevention in Atrial Fibrillation

Renato D. Lopes, MD, PhD, MHS, Duke University School of Medicine, Durham, NC, U.S.

McCormick Place North, N426

Sunday, March 25,2012

9:15 - 9:30 CDT

**ACC Oral Contributions** 

904. Management of the Patient with Atrial Fibrillation: Anticoagulation and Prevention of Stroke-- Joint Oral Arrhythmias Session of the Heart Rhythm Society and the American College of Cardiology

McCormick Place North, N426

Sunday, March 25, 2012

9:30 - 10:30 CDT

**ACC Moderated Poster Contributions** 

1192. Prevention: Clinical Current Topics in Anticoagulation/Antiplatelet Therapies

McCormick Place South, Hall A

Bleeding with Aspirin and Apixaban in Patients University of Unsuitable for Vitamin K Antagonist Therapy: Missouri Scho The AVERROES Study Medicine, Co

Greg C. Flaker, MD, University of Missouri School of Medicine, Columbia, MO, U.S.

Efficacy and Safety of Apixaban Compared with Warfarin for Stroke Prevention in Atrial Fibrillation in Patients Taking Concomitant Aspirin John H. Alexander, MD, MHS, Duke University Medical Center, Durham, NC, U.S. Monday, March 26, 2012

9:30 - 10:30 CDT

**ACC Moderated Poster Contributions** 

1235. Arrhythmias: AF/SVT: Anticoagulation for Atrial Fibrillation: Warfarin and the Newbies

McCormick Place South, Hall A

Comparison of Total Medical Cost Avoidance with the Usage of New Oral Anticoagulants Instead of Warfarin Among Atrial Fibrillation Patients, Based on the ARISTOTLE, RE-LY and ROCKET-AF Trials

Steven Deitelzweig, MD, Ochsner Clinic Foundation, New Orleans, LA, U.S.

### **About Atrial Fibrillation**

Atrial fibrillation is the most common cardiac arrhythmia (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 developing atrial fibrillation is estimated to be approximately twenty five 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, a new oral direct Factor Xa inhibitor, is part of a class of agents being studied for their potential to prevent and treat blood clots.

ELIQUIS is the approved trade name for apixaban in Europe, where it is approved for the prevention of venous thromboembolism (VTE) in adult patients who have undergone elective total hip or knee replacement surgery, and the proposed trade name in the U.S. A regulatory application for stroke prevention in atrial fibrillation was submitted in Europe, which was validated for review by the European Medicines Agency in October 2011.

In November 2011, Pfizer and Bristol-Myers Squibb announced that the U.S. Food and Drug Administration (FDA) accepted for review a New Drug Application (NDA) for ELIQUIS 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 June 28, 2012. ELIQUIS is not approved in the U.S. for any indication.

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 <a href="http://www.bms.com">http://www.bms.com</a> or follow us on Twitter at <a href="http://twitter.com/bmsnews">http://twitter.com/bmsnews</a>.

# Pfizer Inc.: Working together for a healthier world<sup>TM</sup>

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 the compound described in this release will receive regulatory approval for any indication in the U.S. or that it will receive regulatory approval for an additional indication in stroke prevention in atrial fibrillation in the EU. 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 March 21, 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 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 the FDA and the European Medicines Agency regarding whether and when to approve drug applications that have been 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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