

# Bristol-Myers Squibb and Pfizer Announce New Data on Stroke Prevention in Atrial Fibrillation to be Presented at American Heart Association 2012 Scientific Sessions

Thursday, November 01, 2012 - 10:00pm

Data Include Key ELIQUIS Subanalyses from Pivotal ARISTOTLE Trial and Real-World Data on Stroke Prevention Treatment in Atrial Fibrillation

PRINCETON, N.J. & NEW YORK--([BUSINESS WIRE](#))--[Bristol-Myers Squibb Company](#) (NYSE: BMY) and [Pfizer Inc.](#) (NYSE: PFE) today announced that a large number of data presentations sponsored by the companies on ELIQUIS<sup>®</sup> (apixaban) and the treatment of atrial fibrillation will be presented at the American Heart Association 2012 Scientific Sessions, November 3-7, 2012, in Los Angeles, California. Among the presentations are two prespecified subanalyses from the ARISTOTLE trial: a more detailed analysis of ISTH major bleeding with ELIQUIS versus warfarin and an evaluation of the safety and efficacy of ELIQUIS versus warfarin in patients with prior warfarin experience (warfarin-experienced compared with warfarin-naïve). Also being presented is a subanalysis from ARISTOTLE of the safety and efficacy of ELIQUIS versus warfarin in patients with prior coronary artery disease. The ARISTOTLE trial evaluated the efficacy and safety of ELIQUIS, an investigational compound for the prevention of stroke or systemic embolism, in patients with nonvalvular atrial fibrillation compared with warfarin.

Company-sponsored real-world data analyses providing relevant insights on management of atrial fibrillation and experience with warfarin, such as the correlation between bleeding and discontinuation, warfarin outcomes in the real-world compared to trial data, and early ischemic outcomes after warfarin initiation will also be presented.

Details on the ARISTOTLE data analyses and real-world data analyses at the congress are as follows:

## ARISTOTLE SUBANALYSES

Session Details	Presentation Title	Lead Author
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Monday

November 5, 2012

10:45–11:00 PST	Apixaban in Patients with Atrial Fibrillation and Prior Coronary Artery Disease: Insights from the ARISTOTLE Trial	Maria Cecilia Bahit, MD, ECLA, Rosario, Argentina
Abstract Oral Session		
Room 403a		

Monday

November 5, 2012

11:15-11:30 PST	Apixaban versus Warfarin in Patients with Atrial Fibrillation in Relation to Prior Warfarin Use: Insights from the ARISTOTLE Trial	David A. Garcia, MD, University of New Mexico, Albuquerque, NM
Abstract Oral Session		
Hall A-10		

Tuesday

November 6, 2012

3:00–4:30 PST	Reduction in Bleeding with Apixaban versus Warfarin is Consistent Across Subgroups and Locations: Insights from the ARISTOTLE Trial	Elaine M. Hylek, MD, Boston University, Boston, MA
Abstract Poster Session		
Kentia Hall, Core 2, Poster Board: 2068		

## **OUTCOMES RESEARCH/REAL-WORLD DATA**

<b>Session Details</b>	<b>Presentation Title</b>	<b>Lead Author</b>
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Sunday

November 4, 2012

9:30–11:00 PST	Post-Discharge Stroke in Patients With Atrial Fibrillation: A Follow-Up Study in Major Cities of China	Bao Liu, Ph.D., School of Public Health, Fudan University, Shanghai, China
Abstract Poster Session		
Kentia Hall, Core 2, Poster Board: 2117		

Sunday

November 4, 2012

3:00–4:30 PST

Abstract Poster  
Session

The Association Between Bleeding and Warfarin  
Discontinuation in Patients with Atrial Fibrillation

Xianying Pan, Bristol-Myers  
Squibb, Wallingford, CT

Kentia Hall, Core 2,  
Poster Board: 2094

Monday

November 5, 2012

9:30–11:00 PST

Best of AHA  
Specialty  
Conferences

Exposure to Warfarin and the Risks of Stroke and  
Bleeding Events among Patients with Non-Valvular  
Atrial Fibrillation: Real-World vs. Clinical Trial

Alpesh Amin, MD, University  
of California, Irvine, Irvine,  
CA

Tuesday

November 6, 2012

9:30–11:00 PST

Abstract Poster  
Session

Impact of Bleeding on Length of Stay and Total Cost  
in Atrial Fibrillation Patients

Alpesh Amin, MD, University  
of California, Irvine, Irvine,  
CA

Kentia Hall, Core 2,  
Poster Board: 2176

Tuesday

November 6, 2012

9:30–11:00 PST

Abstract Poster  
Session

Evaluation of Patient-Reported Disease Burden of  
Atrial Fibrillation

Liu Xianchen, Pfizer Inc., New  
York, NY

Kentia Hall, Core 2,  
Poster Board: 2177

Tuesday

November 6, 2012

9:30–11:00 PST

Abstract Poster  
Session

Utilization Patterns of Anticoagulants in Non-  
Valvular Atrial Fibrillation after the entry of Novel  
Oral Anticoagulants in the United States

Melissa Hamilton, MPH,  
Bristol-Myers Squibb,  
Princeton, NJ

Kentia Hall, Core 2,  
Poster Board: 2175

Wednesday

November 7, 2012

9:15–9:30 PST

Abstract Oral  
Session

Early Effects on Ischemic Strokes After Initiation of  
Warfarin in Patients With Atrial Fibrillation

Laurent Azoulay, Ph.D., M.Sc.,  
Jewish General Hospital,  
Montreal, Canada

Room 511

Wednesday

November 7, 2012

9:30–11:30 PST

Abstract Poster  
Session

Tolerability of Apixaban — Insights From A Meta-  
Analysis of Discontinuation Rates in Randomized  
Trials

Ria Kundu, MD, University of  
Toledo, Toledo, OH

Kentia Hall, Core 2,  
Poster Board: 2051

### **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.

The companies continue to progress the ELIQUIS application for stroke prevention in atrial fibrillation 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 be granted approval for the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation and with one or more risk factors for stroke. On September 26, 2012, The U.S. Food and Drug Administration (FDA) acknowledged receipt of the ELIQUIS (apixaban) New Drug Application (NDA) resubmission to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation. 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.

ELIQUIS is also 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 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 November 2, 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 (CRL) from the Food and Drug Administration 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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