



# AVERROES Study of Investigational Agent Apixaban Closes Early Due to Clear Evidence of Efficacy

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PRINCETON, N.J. and NEW YORK--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer (NYSE: PFE) today announced that the companies have agreed to stop the Phase 3 AVERROES clinical trial of apixaban in patients with atrial fibrillation. The study will be stopped early because a predefined interim analysis by the independent Data Monitoring Committee (DMC) revealed clear evidence of a clinically important reduction in stroke and systemic embolism in patients with atrial fibrillation considered intolerant of or unsuitable for vitamin K antagonist therapy who received apixaban as compared to aspirin. This interim analysis also demonstrated an acceptable safety profile for apixaban compared to aspirin.

The AVERROES (Apixaban Versus Acetylsalicylic Acid to Prevent Strokes) study included 5,600 patients with atrial fibrillation at risk for stroke who were considered intolerant of or unsuitable for therapy with a vitamin K antagonist such as warfarin. Patients were randomized to receive either apixaban 5mg twice daily or aspirin 81mg to 324 mg once daily. Conducted in 36 countries, the study was coordinated by the Population Health Research Institute (PHRI) at McMaster University and at Hamilton Health Sciences.

The AVERROES investigators have been informed of the decision to stop the study. Bristol-Myers Squibb and Pfizer are working to close out the study and to ensure that patients are informed of the opportunity to start treatment with apixaban in an open-label extension. PHRI will complete a full evaluation of the final AVERROES data set and will seek to publish the results in a peer reviewed journal and present the findings at a scientific congress once the full analysis is complete.

## About the Apixaban Clinical Trial Program

Apixaban, which is currently being developed by Bristol-Myers Squibb and Pfizer, is an investigational oral factor Xa inhibitor, a new class of agents being studied for the prevention and treatment of blood clots. Apixaban 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, including AVERROES.

The apixaban Phase 3 trial program is evaluating the prevention of venous thromboembolism, prevention of stroke and other thromboembolic events in patients with atrial fibrillation, the treatment of venous thromboembolism and secondary prevention of cardiovascular events in patients with acute coronary syndrome.

## About the Bristol-Myers Squibb/Pfizer Collaboration

In 2007, Pfizer and Bristol-Myers Squibb entered into a worldwide collaboration to develop and commercialize apixaban, 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 to maximize the potential benefits of apixaban for patients.

## 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 [www.bms.com](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 or, if approved, that it 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, 2009, 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 10, 2010. 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 a product candidate, apixaban, including its 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 regulatory authorities regarding whether and when to approve any drug applications that may be filed for apixaban as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2009 and in its reports on Form 10-Q and Form 8-K.

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