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Bristol-Myers Squibb And Pfizer Announce Data Presentations For Apixaban At European Society of Cardiology Congress 2011

Monday, August 22, 2011 - 10:00pm

New Data Presentations from Largest Phase 3 Clinical Trial Program for Stroke Prevention in Atrial Fibrillation

(BUSINESS WIRE)--Multiple data presentations for ELIQUIS® (apixaban), an oral direct Factor Xa inhibitor being developed by Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc. (NYSE: PFE), will be given at the European Society of Cardiology Congress, August 27-31, 2011, in Paris, France.

Globally-conducted registrational studies evaluating ELIQUIS for the prevention of stroke in patients with atrial fibrillation will be presented during the congress. Of note is the first presentation of the comprehensive analysis of ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation) during the Hot Line session on Sunday, August 28th.

Presentations on ELIQUIS at the Congress include:

Session Date and Time	**Presentation Title**	**Lead Author**
ARISTOTLE		
Sunday, August 28, 2011 11:54 – 12:07 CEST Hot Line I - Cardiovascular risk and complications Room Paris - Zone F	Efficacy and safety of Apixaban compared to Warfarin for prevention of stroke and systemic embolism in 18,202 patients with atrial fibrillation: primary results of the ARISTOTLE trial	Christopher Granger, MD Duke Clinical Research Institute Durham, NC, U.S.

Sunday, August 28, 2011 14:30 - 14:40 CEST Clinical Trial Update I - Drug treatment Room Paris - Zone F	Efficacy and safety of Apixaban compared to Warfarin at different levels of INR control for stroke prevention in 18,202 patients with atrial fibrillation in the ARISTOTLE trial	Lars Wallentin, MD, PhD Uppsala Clinical Research Center Uppsala, Sweden

AVERROES

Sunday, August 28, 2011 8:30 – 8:45 CEST Room Moscow – Zone B	Efficacy and safety of the novel oral factor Xa inhibitor apixaban in atrial fibrillation (AF) patients with chronic kidney disease (CKD): the AVERROES trial	Robert G. Hart, MD University of Texas Health Science Center, San Antonio, TX, U.S.
Monday, August 29, 2011 8:30 – 12:30 CEST Room Posters – Poster Zone C	Efficacy and safety of apixaban compared with aspirin in patients with atrial fibrillation who previously used and discontinued warfarin therapy: a secondary analysis of the AVERROES trial	John W. Eikelboom, MD Population Health Research Institute Hamilton, Ontario, Canada
Tuesday, August 30, 2011 11:15 – 11:30 CEST Room Sofia – Zone B	Apixaban in patients with atrial fibrillation and their risk for cardiovascular hospitalization: insights from the AVERROES trial	Stefan H. Hohnloser, MD J. W. Goethe University, Frankfurt, Germany

About Atrial Fibrillation

Atrial fibrillation is the most common sustained cardiac arrhythmia. It is estimated that more than 5 million Americans and 6 million individuals in the European Union have AF. The lifetime risk of atrial fibrillation is estimated to be approximately one in four for individuals 40 years of age or older. The underlying threat of 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 in the U.S. are attributable to atrial fibrillation.

About ARISTOTLE and AVERROES

The ELIQUIS stroke prevention in atrial fibrillation clinical trial program was designed to comprehensively evaluate ELIQUIS in approximately 24,000 patients with atrial fibrillation requiring stroke prevention, including patients who are expected or demonstrated to be unsuitable for vitamin K antagonist therapy.

ARISTOTLE, a double-blind, multicenter, head-to-head Phase 3 trial, randomized more than 18,000 patients with atrial fibrillation from over 1,000 centers in about 40 countries. Patients were randomized to receive either ELIQUIS 5 mg twice daily (2.5 mg twice daily in selected patients) or dose-adjusted warfarin (titrated to a target

INR range of 2.0 to 3.0). The key study outcomes were prespecified in a hierarchical manner that sequentially tested ELIQUIS versus warfarin for noninferiority on the composite endpoint of stroke or systemic embolism; superiority on the composite endpoint of stroke or systemic embolism; superiority on major bleeding; and superiority on all-cause death.

The AVERROES study evaluated ELIQUIS compared to aspirin in 5,599 patients with atrial fibrillation at risk for stroke who were demonstrated or expected to be unsuitable for vitamin K antagonist therapy.

About ELIQUIS

ELIQUIS is the approved trade name for apixaban in Europe and the proposed trade name in the United States. ELIQUIS is not approved in any country for the prevention of stroke in patients with atrial fibrillation. Bristol-Myers Squibb and Pfizer recently announced the first regulatory approval for ELIQUIS in the 27 countries of the European Union (EU) for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. Apixaban is not currently approved in the United States.

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, including ARISTOTLE and AVERROES.

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 and the prevention of VTE in hospitalized acutely ill medical patients.

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.

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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.

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 launch of apixaban in the European Union will be a success or that apixaban will become a commercially successful product. There is also no guarantee that apixaban will receive regulatory approval in the United States or regulatory approval for any potential additional indications in the European Union. 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, 2010, 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 August 23, 2011. 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, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates; decisions by regulatory authorities regarding whether and when to approve any drug applications that 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 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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