Bristol-Myers Squibb and Pfizer to Present New Data on Eliquis (apixaban) at the American Heart Association (AHA) Scientific Sessions 2015

Friday, November 06, 2015 - 11:15am

Twenty-two Abstracts to be Presented, Including New Data Analyses from the ARISTOTLE Pivotal Phase 3 Study and Real-World Data Analyses

Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc. (PFE) announced today that 22 abstracts will be presented at the American Heart Association (AHA) Scientific Sessions 2015, to be held November 7-11 in Orlando, Florida. The new data, including four oral presentations, contribute to the Bristol-Myers Squibb and Pfizer Alliance's research in nonvalvular atrial fibrillation (NVAF) and venous thromboembolism (VTE) in patients treated with Eliquis. Abstracts include new data analyses from the pivotal Phase 3 study, ARISTOTLE, as well as a number of real-world data analyses.

"The Alliance is looking forward to sharing new data from both clinical and real-world data analyses," said Douglas Manion, M.D., head of specialty development, Bristol-Myers Squibb. "These data demonstrate the Alliance's commitment to continue to evaluate Eliquis in different settings."

"Clinical trial data are important in evaluating a medicine's efficacy and safety under well-controlled circumstances," said Rory O'Connor, M.D., senior vice president and head of Global Medical Affairs, Global Innovative Pharmaceuticals Business, Pfizer Inc. "These findings can be supplemented by real-world data, offering insight into the use

of Eliquis for its approved indications in routine clinical practice.”

A list of key Alliance presentations is included below. All Alliance titles and abstracts can be accessed on the AHA Scientific Sessions 2015 program planner: http://www.abstractsonline.com/pp8/#!/3795/.

Title

Lead Author

Date / Time

Location /

/ Type

EST

Session –

Orlando

Phase 3 Clinical Trial Subanalyses Polypharmacy and the impact of apixaban on adverse clinical events in patients with atrial fibrillation: insights from the ARISTOTLE trial Jeroen Jaspers Focks / Poster Nov. 8 9:00-10:15 a.m.

A2, Clinical Science, S4087 Efficacy and safety of apixaban compared with warfarin in

patients with atrial fibrillation and normal renal function over time: insights from the ARISTOTLE trial Ziad Hijazi / Poster Nov. 8

9:00-10:15 a.m.

A2, Clinical Science, S4085 Efficacy and safety of apixaban compared with warfarin in patients with peripheral artery disease and nonvalvular atrial fibrillation: insights from the ARISTOTLE trial Peter Hu / Poster Nov. 10
9:00-10:15 a.m.

A2, Clinical Science, T4052 Intracranial Hemorrhage in Patients with Atrial fibrillation in the ARISTOTLE trial: clinical characteristics and associated outcomes Renato D. Lopes / Oral Nov. 10
4:30-4:45 p.m.

W206BC Real-World Data Analyses Poor quality of warfarin therapy is associated with elevated risk of myocardial infarction in patients with atrial fibrillation. Results from the FinWAF registry with 54,568 patients Pekka Raatikainen / Poster Nov. 8
9:00-10:15 a.m.

A2, Clinical Science, S4064 Real-world comparison of major bleeding risk among nonvalvular atrial fibrillation patients newly initiated on warfarin versus apixaban 5 mg BID, dabigatran 150 mg BID, or rivaroxaban 20 mg QD Shital Kamble / Oral Nov. 8
4:00-4:15 p.m.

W311CD Comparison of major bleeding risk and associated costs among newly anticoagulated nonvalvular atrial fibrillation patients Steve Deitelzweig / Oral Nov. 8
4:15-4:30 p.m.

W312C, 167 Comparison of major bleeding risk and healthcare costs among treatment-naïve nonvalvular atrial fibrillation patients initiating apixaban, dabigatran, rivaroxaban, or warfarin Alpesh Amin / Poster Nov. 9
9:00-10:15 a.m.

A2, Population Science, M2075 Clinical and demographic characteristics according to dosage among new initiators and/or switchers from warfarin nonvalvular atrial fibrillation patients on apixaban, dabigatran and rivaroxaban Ping Tepper / Poster Nov. 9
9:00-10:15 a.m.

A2, Population Science, M2069 Real-world assessment of patients switching from warfarin to non-vitamin K oral anticoagulants (NOACs) using MarketScan EarlyView data

Cristina Masseria / Poster Nov. 9
9:00-10:15 a.m.

A2, Population Science, M2071 Comparison of all-cause and bleeding-related hospitalizations among nonvalvular atrial fibrillation patients receiving oral anticoagulants Steve Deitelzweig / Poster Nov. 9
9:00-10:15 a.m.

A2, Population Science, M2070 The profile of new users of warfarin and non-vitamin K oral anticoagulants in patients with nonvalvular atrial fibrillation Gunnar Gislason / Poster Nov. 9
2:00-3:15 p.m.

A2, Clinical Science, M4466 Outcomes associated with warfarin time in therapeutic range among nonvalvular atrial fibrillation patients treated in an integrated healthcare delivery system in the U.S. Steve Deitelzweig / Poster Nov. 9
2:00-3:30 p.m.

Valencia Ballroom, W415 Risk of stroke, bleeding events and mortality is strongly associated with the quality of warfarin therapy. Results from the FinWAF registry with 54,568 patients Mika Lehto / Oral Nov. 9
5:45-6:00 p.m.

W204, 376 Is major bleeding risk for oral anticoagulants similar among newly initiated nonvalvular atrial fibrillation patients? Gregory Lip / E-Abstract Session Nov. 10
9:10-9:20 a.m.

A2, Population Science Theater, 838 Venous thromboembolism recurrence and bleeding risk among cancer patients using a large commercial database Cristina Masseria / Poster Nov. 10
2:00-3:15 p.m.

A2, Population Science, T2108 Hospitalization rates and healthcare costs among nonvalvular atrial fibrillation patients who were naïve users of novel oral anticoagulants Amanda Bruno / Poster Nov. 10
2:00-3:30 p.m.

Valencia Ballroom, W415AB Healthcare costs following stroke and major bleeding events in nonvalvular atrial fibrillation patients Gerald Naccarelli / Poster Nov. 10

2:00-3:30 p.m.

Valencia Ballroom, W415 Comparison of hospital length of stay and costs between nonvalvular atrial fibrillation patients treated with either apixaban or warfarin Lin Xie / Poster Nov. 10
2:00-3:30 p.m.

Valencia Ballroom, W415 An early assessment of hospital readmissions among nonvalvular atrial fibrillation treated with the new oral anticoagulants, apixaban, dabigatran, and rivaroxaban Steve Deitelzweig / Poster Nov. 10
2:00-3:30 p.m.
Valencia Ballroom, W415

About Eliquis

Eliquis (apixaban) is an oral selective Factor Xa inhibitor. By inhibiting Factor Xa, a key blood clotting protein, Eliquisdecreases thrombin generation and blood clot formation. Eliquis is approved for multiple indications in the U.S. based on efficacy and safety data from seven Phase 3 clinical trials. Eliquis is a prescription medicine indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF); for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery; for the treatment of DVT and PE; and to reduce the risk of recurrent DVT and PE, following initial therapy.

ELIQUIS Important Safety Information and Indications

ELIQUIS Important Safety Information
WARNING: (A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA (A) Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events. If anticoagulation with ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant. (B) Epidural or spinal hematomas may occur in patients treated with ELIQUIS who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include: use of indwelling epidural catheters concomitant

use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants a history of traumatic or repeated epidural or spinal punctures a history of spinal deformity or spinal surgery optimal timing between the administration of ELIQUIS and neuraxial procedures is not known Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated.

CONTRAINDICATIONS

Active pathological bleeding Severe hypersensitivity reaction to ELIQUIS (e.g., anaphylactic reactions)
WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant. Bleeding Risk: ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding. Concomitant use of drugs affecting hemostasis increases the risk of bleeding, including aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs. Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage. There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). A specific antidote for ELIQUIS is not available. Spinal/Epidural Anesthesia or Puncture: Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis. The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS. The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours. Monitor patients frequently and if neurological compromise is noted, urgent diagnosis and treatment is

necessary. Physicians should consider the potential benefit versus the risk of neuraxial intervention in ELIQUIS patients. Prosthetic Heart Valves: The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients. Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolysis or Pulmonary Embolectomy: Initiation of ELIQUIS is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

The most common and most serious adverse reactions reported with ELIQUIS were related to bleeding.

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be noncritical in location and easily controlled. Bridging anticoagulation during the 24 to 48 hours after stopping ELIQUIS and prior to the intervention is not generally required. ELIQUIS should be restarted after the surgical or other procedures as soon as adequate hemostasis has been established.

DRUG INTERACTIONS

Strong Dual Inhibitors of CYP3A4 and P-gp: Inhibitors of cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with strong dual inhibitors of CYP3A4 and P-gp. Strong Dual Inducers of CYP3A4 and P-gp: Avoid concomitant use of ELIQUIS with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John’s wort) because such drugs will decrease exposure to apixaban and increase the risk of stroke and other thromboembolic events. Anticoagulants and Antiplatelet Agents: Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

PREGNANCY CATEGORY B

There are no adequate and well-controlled studies of ELIQUIS in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. ELIQUIS should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.
Please see full Prescribing Information, including BOXED WARNINGS and Medication Guide, available atwww.bms.com.

Indications

ELIQUIS is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

ELIQUIS is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

ELIQUIS is indicated for the treatment of DVT and PE, and to reduce the risk of recurrent DVT and PE following initial therapy.

About ARISTOTLE

ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation) was designed to evaluate the efficacy and safety of Eliquis versus warfarin for the prevention of stroke or systemic embolism. In ARISTOTLE, 18,201 patients were randomized (9,120 patients to Eliquis and 9,081 to warfarin). ARISTOTLE was an active-controlled, randomized, double-blind, multi-national trial in patients with nonvalvular atrial fibrillation or atrial flutter, and at least one additional risk factor for stroke. Patients were randomized to treatment with Eliquis 5 mg orally twice daily (or 2.5 mg twice daily in selected patients, representing 4.7 percent of all patients) or warfarin (target INR range 2.0-3.0), and followed for a median of 1.8 years.

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 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 visitwww.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

About Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, 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. 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, 2014, 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 6, 2015. 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 Eliquis (apixaban), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates as well as the possibility of unfavorable clinical trial results; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Eliquis; 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, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov andwww.pfizer.com.

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