Bristol-Myers Squibb and Pfizer to Present New Eliquis (apixaban) Analyses at ESC Congress 2016

Tuesday, August 23, 2016 - 02:59am

Nineteen abstracts to be presented, including new post-hoc sub-analyses from the ARISTOTLE Phase 3 trial and multiple retrospective real-world data analyses from ACROPOLIS

Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc.(NYSE: PFE) announced today that 19 abstracts (late-breaking, rapid-fire, oral and poster presentations) will be presented at ESC Congress 2016, to be held August 27–31 in Rome, Italy. These new data from post-hoc analyses from ARISTOTLE (Apixaban for Reduction In STroke and Other T hromboembolic Events in Atrial Fibrillation) and retrospective real-world data analyses continue to underscore the Alliance's commitment to the evaluation of Eliquisfor patients with nonvalvular atrial fibrillation (NVAF) and venous thromboembolism (VTE). Of note, several of the real-world data analyses are part of ACROPOLIS™ (Apixaban ExperienCe Through Real-WOrld POpuLatIon Studies), a global real-world data research program designed to further evaluate the effectiveness and safety of apixaban in routine clinical practice.

"The Bristol-Myers Squibb and Pfizer Alliance is pleased to share 19 abstracts, which include new real-world analyses, as well as new sub-analyses from the pivotal Phase 3 ARISTOTLE trial," said Rory O'Connor, M.D., Chief Medical Officer, Internal Medicine, Pfizer Innovative Health. "We look forward to the opportunity to contribute to the scientific discussion and continued research during ESC Congress 2016."

“As patient and provider needs continue to evolve, it’s essential that we deepen our understanding of how medicines are working in real-world situations,” said Jack Lawrence, M.D., Vice President, Cardiovascular Specialty Development, Bristol-Myers Squibb. “This year at ESC Congress 2016, we’ll be discussing new NVAF and VTE data that complement our robust body of clinical trial data.”

The complete list of Bristol-Myers Squibb and Pfizer Alliance presentations is included below. Abstracts can be accessed on the ESC Congress 2016 website.

Title Presenting Author/Type Date/Time (BST) Location/Session Phase 3 Clinical Trial Sub-Analyses
Patients with Atrial Fibrillation and History of Falls Are at High Risk for Bleeding but Have Less Bleeding with Apixaban than Warfarin: Results from the ARISTOTLE Trial

Session: New Trends in Antithrombotic Therapy for Atrial Fibrillation

Rao et al. / Oral, Rapid Fire
Aug. 28, 11:10

Agora 1 – Poster Area
Efficacy and Safety of Apixaban versus Warfarin in Patients with Atrial Fibrillation and Active Cancer: Insights from the ARISTOTLE Trial

Session: New Trends in Antithrombotic Therapy for Atrial Fibrillation

Melloni et al. / Oral, Rapid Fire
Aug. 28, 11:20

Agora 1 – Poster Area
Patients with Atrial Fibrillation Treated with Apixaban Are Less Likely to Discontinue Study Drug When Compared with Warfarin: Insights from the ARISTOTLE Trial

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation III

Xavier et al. / Poster

Aug. 28, 14:00

Poster Area Real-World Data and Other Analyses

Contemporary Results from EHR Study of Real-World Bleeding Risk among Elderly and Overall Non-Valvular Atrial Fibrillation Patients Prescribed Apixaban, Dabigatran, Rivaroxaban and Warfarin

Session: New Trends in Antithrombotic Therapy for Atrial Fibrillation

Horblyuk et al. / Oral, Rapid Fire
Aug. 28, 12:00

Agora 1 – Poster Area
Real-World Comparisons of Major Bleeding Risk and Major Bleeding-Related Hospitalization Costs among Elderly Non-Valvular Atrial Fibrillation Patients Newly Initiated on Apixaban or Warfarin

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation

Lip et al. /

Poster

Aug. 28, 14:00

Poster Area
Is Major Bleeding Risk for Oral Anticoagulants Similar Between Non-Valvular Atrial Fibrillation Patients Newly Initiated on Warfarin and Propensity-Score Matched NOAC Initiators? A Real World Study

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation

Lip et al. / Poster
Aug. 28, 14:00

Poster Area
Major Bleeding Risk in Patients 75 Years of Age or Older with Non-Valvular Atrial Fibrillation Initiating Oral Anticoagulants: A ‘Real-World’ Comparison of Warfarin, Apixaban, Dabigatran, or Rivaroxaban

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation II

Lip et al. /

Poster

Aug. 28, 14:00

Poster Area
Is There a Difference in Treatment Persistence Across Oral Anticoagulants? Results of a UK Cohort Study Evaluating Oral Anticoagulation Therapy in an Atrial Fibrillation Population

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation

Stynes et al. / Poster
Aug. 28, 14:00

Poster Area
Real-World Comparison of Major Bleeding and Associated Costs among Treatment-Naïve Non-Valvular Atrial Fibrillation Patients Initiating Apixaban or Warfarin

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation II

Trocio et al. / Poster
Aug. 28, 14:00

Poster Area
Aspirin, not without Bleeding Risk in the Real World: Results of a UK Cohort Study Evaluating the Use of Antiplatelet Therapy for Stroke Prevention in Atrial Fibrillation (AF)

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation III

Ridha et al. / Poster
Aug. 28, 14:00

Poster Area
Is Aspirin Monotherapy Effective for Stroke Prevention in the Real World? A UK Cohort Study Evaluating the Incidence of Stroke in the Absence of Anticoagulation in Atrial Fibrillation (AF)

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation II

Ridha et al. /

Poster

Aug. 28, 14:00

Poster Area Differences in the Characteristics of Patients with Non-Valvular Atrial Fibrillation Who Are Newly Prescribed Apixaban, Rivaroxaban, Dabigatran and VKA in General Practice in the UK
Session: Poster Session 3: Anticoagulation in Atrial Fibrillation

Stynes et al. / Poster

Aug. 28, 14:00

Poster Area
Risk of Bleeding with Non-Vitamin K Antagonists and Phenprocoumon in Routine Care Patients with Non-Valvular Atrial Fibrillation

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation III

Hohnloser et al. / Poster

Aug. 28, 14:00

Poster Area
Are Your Atrial Fibrillation (AF) Patients Protected from Ischaemic Stroke? Clinical Characteristics of AF Patients Eligible for Stroke Prevention but Remaining Untreated in UK Clinical Practice

Session: Poster Session 3: Anticoagulation in Atrial Fibrillation II

Ridha et al. / Poster

Aug. 28, 14:00

Poster Area
Bleeding Risk for Non-Valvular AF Patients Prescribed Warfarin, or Standard Doses of Apixaban 5mg BID, Dabigatran 150mg BID or Rivaroxaban 20mg QD in Real-World Practice: Findings from EHR

Session: Are You Still Afraid about Bleeding Risk of Antithrombotic Therapy in Atrial Fibrillation?

Lip et al. / Oral, Advances in Science
Aug. 28, 14:18

Minsk – Village 4
Demographic and Clinical Characteristics Associated with Initiation of Individual Oral Anticoagulants among Patients with Newly Diagnosed Venous Thromboembolism

Session: Poster Session 4: Thrombosis and Coagulation

Li et al. / Poster
Aug. 29, 08:30

Poster Area
A Nationwide Register Study to Compare Bleeding Rates in Patients with Non-Valvular Atrial Fibrillation Prescribed Oral Anticoagulants

Session: Registries Atrial Fibrillation

Halvorsen et al. / Late-Breaker

Aug. 29, 08:45

Raphael – The Hub
Costs of Major Adverse Outcomes in Patients with Incident Venous Thromboembolism in Clinical Practice in the United Kingdom

Session: Advances in Pulmonary Embolism

Cohen et al. / Poster

Aug. 29, 16:03

Moderated Poster Station – Poster Area
Potential Impact of Apixaban on Hospital Resource Use in Patients with Venous Thromboembolism

Session: Antithrombotics in Daily Clinical Practice

Li et al. / Oral, Rapid Fire
Aug 30, 17:24
Galileo – The Hub

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 Indications and Important Safety Information

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.

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.

About ACROPOLIS™

ACROPOLIS™ (Apixaban ExperienCe Through Real-WOrld POpuLatIon Studies) is the Eliquis (apixaban) global real-world data program designed to generate additional evidence from routine clinical practice settings to further inform healthcare decision makers, including healthcare providers and payers. The ACROPOLIS program will include retrospective, outcomes-based analyses from over 10 databases around the world, including medical records, medical and pharmacy health insurance claims data, and national health data systems.

Analyses of real-world data allow for a broader understanding of patient outcomes associated with Eliquis outside of the clinical trial setting, as well as insight into other measures of healthcare delivery, such as hospitalization and costs.

About ARISTOTLE

ARISTOTLE (Apixaban for Reduction In STroke and Other ThromboembоLic 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 about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

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. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizerand @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

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, 2015, 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, 2016. 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, 2015 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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