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Bristol-Myers Squibb and Pfizer to Deliver 12 New Eliquis® (apixaban) Presentations at American Heart Association (AHA) Scientific Sessions 2016

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New research includes final data from AEGEAN, new real-world data analyses from the ACROPOLIS program, and sub-analyses from the pivotal ARISTOTLE program

Bristol-Myers Squibb Company (NYSE:BMY) and Pfizer Inc.(NYSE:PFE) announced today that 12 *Eliquis* abstracts will be presented at the AHA Scientific Sessions 2016, to be held November 12-16 in New Orleans. Among these abstracts, the Bristol Myers-Squibb and Pfizer Alliance will present final data from the randomized AEGEAN (**A**ssessment of an **E**ducational and **G**uidance Program for ***E****liquis* **A**dherence in **N**onvalvular Atrial Fibrillation) study, highlighting adherence and persistence data for nonvalvular atrial fibrillation (NVAF) patients treated with *Eliquis* to reduce the risk of stroke. These data are based on an evaluation of an additional education program versus standard of care patient education. Additional post-hoc analyses from the pivotal ARISTOTLE (**A**pixaban for **R**eduction **I**n **ST**roke and **O**ther **T**hromboembo**L**ic **E**vents in Atrial Fibrillation) study and retrospective real-world data analyses from ACROPOLIS (**A**pixaban Experien**C**e Through **R**eal-W**O**rld **PO**pu**L**at**I**on **S**tudies) will also be presented.

“We are proud to build on the growing body of clinical and real-world evidence for the use of *Eliquis,”* said Rory O’Connor, M.D., Chief Medical Officer, Internal Medicine, Pfizer Innovative Health. “At this year’s AHA Scientific Sessions, we’ll also share data on patient adherence to anticoagulant therapy, which is critical for the reduction of stroke risk in patients with nonvalvular atrial fibrillation.”

“As part of our steadfast commitment to the ongoing evaluation of *Eliquis,* we continue to gather insights from real-world practice to complement the results we’ve seen in randomized clinical trials,” said Christoph Koenen, M.D., MBA, VP, Development Lead, *Eliquis*, Bristol-Myers Squibb. “These analyses form part of our ACROPOLIS global real-world data program, which evaluates data from regions around the world collected through medical records, insurance claims databases and national health data systems to further inform healthcare decision-making.”

The complete list of Bristol-Myers Squibb and Pfizer Alliance presentations is included below. Abstracts can be accessed on the AHA Scientific Session 2016 planner.

Title	Presenting Author/Type	Date/Time (CST)	Location/Session
Phase 3 Clinical Trial Sub-Analyses			

Use of the Novel Biomarker-based ABC Bleeding Risk Score Over Time in Atrial Fibrillation: Insights from the ARISTOTLE Trial *Session: Arrhythmia: Clinical Electrophysiology, Diagnosis and Risk Stratification VII*	Hijazi et al./ Oral	Nov. 14, 2:00-3:15 PM	Science and Technology Hall, Clinical Science II Section
Percutaneous Coronary Intervention and Antiplatelet Therapy on Apixaban or Warfarin: Insights from the ARISTOTLE Trial *Session: Antiplatelet Therapy for PCI and ACS: Insights from Large Trials and Registries*	Kopin et al./ Poster	Nov. 13, 3:45 PM	Science and Technology Hall, Clinical Science Section
Adherence and Persistence to Apixaban Treatment in Patients with Non-Valvular Atrial Fibrillation is High and Similar with Standard-of-care Patient Education or with an Additional Educational Program: The Randomized AEGEAN study *Session: Cardiovascular Stroke*	Montalescot et al./ Oral	Nov. 13, 5:45-5:55 PM	Room 348-349
A History of GI Bleeding is associated with Increased Risk of Subsequent Bleeding, but not Stroke: Insights from the ARISTOTLE Trial *Session: Treatment of Arrhythmias: Pharmacologic II*	Lopes et al./ Poster	Nov. 15, 1:30 PM	Science and Technology Hall, Clinical Science Section
Risk Factors for Cause-Specific Mortality in Patients Anticoagulated for Atrial Fibrillation: Insights From the ARISTOTLE trial *Session: Clinical Risk Factors and Novel Biomarkers: Diagnostic, Prognostic, and Therapeutic Implications*	Sharma et al./ Rapid-Fire	Nov. 15, 2:25 PM	Science and Technology Hall, Population Science Theater

Biomarkers Predict Cause of Death More Accurately than Clinical Variables in Patients with Atrial Fibrillation on Oral Anticoagulation – Results from the ARISTOTLE trial *Session: Chronic and Acute Ischemic Heart Disease*	Hijazi et al./ Rapid-Fire	Nov. 15, 6:30-6:40 PM	Room 228-230
Real-World Data and Other Analyses Outcomes Associated with Warfarin Time in Therapeutic Range among Veterans with Non-Valvular Atrial Fibrillation in the US, 2005-2015 *Session: Issues in Atrial Fibrillation and Anticoagulation*	Liu et al./ Rapid-Fire	Nov. 14, 12:10 PM	Science and Technology Hall, Population Science Theater
Real World Bleeding Risks in Non-Valvular Atrial Fibrillation Patients with Heart Failure: Contemporary EHR Results Among Prescribed Apixaban, Dabigatran, Rivaroxaban and Warfarin *Session: Issues in Atrial Fibrillation and Anticoagulation*	Masseria, C. et al./ Rapid-Fire	Nov. 14, 12:20 PM	Science and Technology Hall, Population Science Theater
Real-World Comparisons of Major Bleeding Risk for Commercially Insured Non-Valvular Atrial Fibrillation Patients Initiating Apixaban, Dabigatran, Rivaroxaban, or Warfarin *Session: Patient Centered Outcomes Research in Atrial Fibrillation and Anticoagulation*	Amin et al./ Poster	Nov. 14, 2:00 PM	Science and Technology Hall, Population Science Section
Real World Comparisons of Major Bleeding Risk Stratified by CHA_2DS_2-VASc Scores among Non-Valvular Atrial Fibrillation Patients Initiating Apixaban or Warfarin *Session: Patient Centered Outcomes Research in Atrial Fibrillation and Anticoagulation*	Lip et al./ Poster	Nov. 14, 2:00 PM	Science and Technology Hall, Population Science Section

Performance of the Novel Biomarker-Based ABC-Stroke Risk Score over Time in Patients with Atrial Fibrillation *Session: Arrhythmia: Clinical Electrophysiology, Diagnosis and Risk Stratification V*	Hijazi et al./ Oral	Nov. 14, 2:00 PM	Science and Technology Hall, Clinical Science II Section
Real-world Evaluation of Healthcare Resource Use and Costs of Elderly Patients with Non-Valvular Atrial Fibrillation Treated with Apixaban vs. Warfarin in the US *Session: Resource Intensity, Costs, and Cost-Effectiveness in CVD*	Deitelzweig et al./ Poster	Nov. 15, 1:30 PM	Science and Technology Hall, Population Science Section

About *Eliquis*

Eliquis (apixaban) is an oral selective Factor Xa inhibitor. By inhibiting Factor Xa, a key blood clotting protein, *Eliquis* decreases 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

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 at www.bms.com.

About ACROPOLIS™

ACROPOLIS™ (**A**pixaban Experien**C**e Through **R**eal-W**O**rld **PO**pu**L**at**I**on **S**tudies) 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 (**A**pixaban for **R**eduction **I**n **ST**roke and **O**ther **T**hromboembo**L**ic **E**vents 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 @Pfizer and @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 November 10, 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, including unfavorable new clinical data and additional analyses of existing clinical data; 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 and www.pfizer.com.

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