Pfizer Logo

# New Data Presented On Phase 3 Trial Of ELIQUIS® (apixaban) In The Prevention Of Venous Thromboembolism In Patients With Acute Medical Illness

Saturday, November 12, 2011 - 09:31pm

In ADOPT, Apixaban did not Meet the Primary Efficacy Outcome of Superiority to Enoxaparin for the Endpoint of VTE and VTE-related Death Numerically Lower Number of Events Observed in the Apixaban Arm Did not Meet Statistical Significance Key Safety Outcome of Major Bleeding Occurred More in the Apixaban Arm and was Low in Both Groups

"Solving the problem of VTE post-hospitalization remains a critical unmet need in preventing medically ill patients from developing deep vein thrombosis and pulmonary embolism,"

(BUSINESS WIRE)--Bristol-Myers Squibb *C*ompany (NYSE: BMY) and Pfizer Inc. (NYSE: PFE) today announced the results of the Phase 3 ADOPT (Apixaban Dosing to Optimize Protection from Thrombosis) trial, which evaluated apixaban versus enoxaparin in acutely ill medical patients, did not meet the primary efficacy outcome of superiority to enoxaparin for the endpoint of venous thromboembolism (VTE) and VTE-related death at day 30. The apixaban arm had a 13 percent lower rate of events than enoxaparin followed by placebo, which favored apixaban but was not statistically significant and thus no clinically directive conclusion can be drawn. The key safety outcome of major bleeding was low in both groups but occurred in more patients treated with apixaban than with enoxaparin (0.47 percent of patients in the apixaban group and 0.19 percent of patients in the enoxaparin group (P=0.04)). The study results were presented during a late-breaking session at the annual American Heart Association (AHA) Scientific Sessions in Orlando, FL, and published in the *New England Journal of Medicine*.

“Solving the problem of VTE post-hospitalization remains a critical unmet need in preventing medically ill patients from developing deep vein thrombosis and pulmonary embolism,” said Dr. Samuel Z. Goldhaber, senior cardiologist at Brigham and Women’s Hospital, and Professor of Medicine, Harvard Medical School, Boston, MA. “ADOPT provides important insights for clinical trialists designing studies of extended duration VTE prophylaxis among medically ill hospitalized patients."

ELIQUIS ® (apixaban), a new oral direct Factor Xa inhibitor, is part of a class of agents being studied for their potential to prevent and treat blood clots in multiple indications. ELIQUIS is currently approved in the 27 countries of the European Union (EU) for the prevention of VTE in adult patients who have undergone elective total hip or knee replacement surgery.

**About ADOPT**

ADOPT was a Phase 3, international, multicenter, randomized, double-blind, controlled study that compared apixaban to enoxaparin in acutely ill medical patients. Patients hospitalized with an expected stay of at least three days were randomly assigned to either oral apixaban (2.5 mg twice daily) for 30 days or to subcutaneous

enoxaparin (40 mg once daily). Patients in the enoxaparin arm received treatment for a minimum of 6 days and a maximum of 14 days. Patients randomized to apixaban received daily injections of enoxaparin placebo for a minimum of 6 days and patients randomized to enoxaparin received apixaban placebo tablets for 30 days.

Of the 6,758 patients from 35 countries enrolled in the study, 6,528 patients were randomized for the analysis of the primary efficacy outcome defined as the composite of VTE-related death, fatal or non-fatal pulmonary embolism (PE), symptomatic or asymptomatic deep vein thrombosis (DVT) as detected by ultrasound and occurring within the 30-day intended treatment period. The statistical plan for the study required testing superiority of apixaban during the intended treatment period before testing for non-inferiority in the injectable treatment period.

When apixaban was compared to enoxaparin, the primary efficacy endpoint occurred in 2.71 percent of patients in the apixaban group and 3.06 percent of patients in the enoxaparin group, demonstrating a non-significant relative risk reduction for apixaban of 13 percent that was not superior to a shorter course of enoxaparin (P=0.44).

In ADOPT, the rate of dropouts was higher than expected across both treatment arms, including loss of patients to ultrasound examinations, and a lower than expected overall event rate, both of which contributed to the study being underpowered.

The key safety outcome of major bleeding was low in both groups but occurred in more patients treated with apixaban for 30 days than with enoxaparin for a minimum of six days and a maximum of 14 days. At Day 30, major bleeding occurred in 0.47 percent of patients in the apixaban group and 0.19 percent of patients in the enoxaparin group (P=0.04). Major and clinically relevant non-major bleeding occurred in 2.67 percent of patients who received apixaban and in 2.08 percent of patients who received enoxaparin (P=0.12).

Other measures of overall safety were similar for apixaban and enoxaparin in ADOPT. Among the safety endpoints of adverse events, serious adverse events, deaths, discontinuation due to AEs, and liver function test (LFT) elevations; apixaban appeared to be similar to enoxaparin.

**About Venous Thromboembolism**

Venous thromboembolism encompasses two serious conditions: deep vein thrombosis, a blood clot in a vein, usually in the leg that partially or totally blocks the flow of blood; and pulmonary embolism, a blood clot blocking a vessel in the lungs. Deep vein thrombosis causes multiple symptoms including pain, swelling and redness and, more importantly, can progress to pulmonary embolism, which carries the risk of sudden death.

**About ELIQUIS**

ELIQUIS is the approved trade name for apixaban in Europe and the proposed trade name in the U.S. The companies recently announced the regulatory application for stroke prevention in atrial fibrillation was validated for review by the European Medicines Agency. The alliance expects to have an accepted filing in the U.S. for this indication by the end of 2011.

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 ADOPT. ELIQUIS is currently being evaluated in ongoing trials for the treatment of recurrent VTE, in the Phase 3 AMPLIFY and AMPLIFY-EXT trials.

**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.

**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. -6-

***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 companies will submit regulatory filings for apixaban for an indication in VTE prevention or that apixaban would receive regulatory approval for such indication. There is also no guarantee that, if approved in this indication, apixaban 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, 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 November 13, 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 have been or 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.*

## Multimedia Files:

Download All Files
Preview image

Download:
Download ViewImage (19.24 KB)
Download Web Ready (23.89 KB)
Download Thumbnail (17.34 KB)

Bristol-Myers Squibb Chrissy Trank (Media), 609-252-3418 christina.trank@bms.com or John Elicker (Investors), 609-252-4611 john.elicker@bms.com or Pfizer Inc. MacKay Jimeson (Media), 212-733-2324 MacKay.Jimeson@pfizer.com or Suzanne Harnett (Investors), 212-733-8009 Suzanne.Harnett@pfizer.com