

Bristol-Myers Squibb and Pfizer Initiate New Study in the Apixaban Phase 3 Clinical Trial Program

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First patient dosed in 12-month study examining the effects of the investigational drug apixaban in patients with blood clots in the leg veins or lungs

[\(BUSINESS WIRE\)](#)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer (NYSE: PFE) announced today the start of a new Phase 3 clinical trial to assess the effect of apixaban in patients with venous thromboembolism (VTE), a potentially fatal disease process that begins with blood clots in the leg veins or lungs. Apixaban, which is currently being developed by the two companies, is an investigational oral, highly selective factor Xa inhibitor, a new class of agents with therapeutic potential to prevent and treat blood clots.

The AMPLIFY (Apixaban after the initial Management of Pulmonary embolism and deep vein thrombosis with First-line therapy) trials are part of the EXPANSE program - the global Phase 3 clinical development trial program for apixaban. AMPLIFY and AMPLIFY-EXT are two major clinical trials involving approximately 7,300 patients with deep vein thrombosis (DVT), a blood clot in the vein, or pulmonary embolism (PE), a potentially fatal condition caused by a blood clot blocking a vessel in the lung.

“The initiation of this apixaban Phase 3 trial represents Bristol-Myers Squibb’s and Pfizer’s commitment to furthering research in the treatment of VTE, a serious disease that affects 1.3 million people annually in the US and Europe,” said Jack Lawrence, Vice President, Research and Development, Bristol-Myers Squibb. “Current oral drug treatment options for the treatment of patients with VTE are primarily vitamin K antagonists (VKA), such as warfarin. Limitations of VKAs include a slow onset of action, a narrow therapeutic window necessitating regular coagulation monitoring and dose adjustment, and multiple food and drug interactions.”

New Apixaban Phase 3 Clinical Trials

The AMPLIFY-EXT (Apixaban after the initial Management of PuLmonary embolism and deep vein thrombosis with First-line therapY- EXTended treatment) trial has initiated enrollment and will include approximately 2,430 patients who will receive, for an extended 12-month period, apixaban 2.5 mg dose or 5 mg twice daily compared to patients taking placebo to determine the effects of apixaban on recurrent VTE. Prior to entering the trial, patients will have completed 6 to 12 months of treatment for DVT or PE.

The AMPLIFY trial is expected to begin in the next few months, and will enroll approximately 4,800 patients with acute DVT or PE and will investigate the safety and efficacy of apixaban 10 mg twice daily for 1 week followed by 5 mg twice daily for 6 months compared to enoxaparin plus warfarin, the two drugs used as the current standard of care.

About Venous Thromboembolism (VTE)

Venous thromboembolism can take two forms: either as a deep vein thrombosis (DVT), a blood clot in a vein, usually in the leg that partially or totally blocks the flow of blood, or as a pulmonary embolism (PE), a blood clot blocking a vessel in the lungs. PE can be associated with significant hemodynamic deterioration or death.

VTE continues to be a major cause of morbidity and mortality in the western world, with an incidence of one to two per 1000 people, and represents one in 10 hospital deaths. In addition, post-thrombotic syndrome and pulmonary hypertension occur in 10 percent of DVT and five percent of PE patients, respectively.

The first year incidence of recurrent VTE is approximately 7.7 percent, and the risk of recurrence continues after anticoagulant treatment ends at an average of 3% per year over the next ten years.

About the Apixaban Phase 3 Program: EXPANSE

The EXPANSE apixaban clinical trial program has seven ongoing Phase 3 clinical studies involving approximately 45,000 patients worldwide. In addition to the recently initiated VTE treatment program, the EXPANSE program also includes trials studying potential use for prevention of venous thromboembolism in patients undergoing orthopedic surgery and in hospitalized medically ill patients at high risk of VTE, and trials studying prevention of stroke and other thromboembolic events in patients with atrial fibrillation (AF). The VTE prevention program consists of:

- ADVANCE-1, 2, and 3 trials are investigating the safety and efficacy of apixaban 2.5 mg twice daily compared to enoxaparin in patients undergoing major orthopedic surgery. Results from the first trial are targeted for presentation at the American Society of Hematology in December 2008.
- The ADOPT study is investigating apixaban 2.5 mg twice daily for one month compared to standard of care (enoxaparin for at least 6 days followed by placebo) for the prevention of VTE in hospitalized patients who are medically ill and at risk of VTE.

Apixaban is also in Phase 3 trials studying the prevention of thrombotic events, such as stroke in patients with atrial fibrillation (AF). The AF program consists of:

- The ARISTOTLE trial, which is investigating apixaban 5 mg twice daily compared to warfarin in approximately 15,000 patients with atrial fibrillation.
- The AVERROES trial, which is investigating apixaban 5 mg twice daily compared to aspirin in approximately 5,600 patients with atrial fibrillation who are ineligible for VKA treatment or haven't tolerated previous VKA treatment.

Apixaban has also recently completed enrollment in a Phase 2 trial in patients with acute coronary syndrome (the APPRAISE trial). The results of this trial will be presented at the European Society of Cardiology meeting in September 2008.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information visit www.bms.com.

About Pfizer

Founded in 1849, Pfizer is the world's largest research-based pharmaceutical company. Pfizer is taking new approaches to advancing better health as it discovers, develops, manufactures and delivers quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. Pfizer also

partners with healthcare providers, governments and local communities around the world to expand access to medicines and to provide better quality health care and health system support. At Pfizer, more than 85,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide. For more information visit www.pfizer.com.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of June 10, 2008. Pfizer assumes no obligation to update any 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 a product candidate, apixaban, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2007 and in its reports on Form 10-Q and Form 8-K.

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