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Bristol-Myers Squibb and Pfizer Provide Update on Apixaban Clinical Development Program

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Apixaban Phase II Acute Coronary Syndrome Data to be Presented at European Society of Cardiology Meeting on Sept. 2 U.S. Regulatory Filing for the Prevention of Venous Thromboembolism will not be submitted in 2009, as previously indicated Other Clinical Programs Continue as Planned

(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc (NYSE: PFE) provided an update on the apixaban clinical development program today. The companies announced that new Phase II data in acute coronary syndrome patients (ACS) will be presented at the upcoming meeting of the European Society of Cardiology (ESC). In addition, Bristol-Myers Squibb and Pfizer reported that an early evaluation of results from a Phase III study of apixaban for the prevention of venous thromboembolism (VTE) in patients undergoing total knee replacement indicates that the primary endpoint of this study was not met.

The Phase III VTE prevention study known as ADVANCE-1 compared apixaban, a novel, oral Factor Xa inhibitor given at a dose of 2.5 mg, twice daily, to the FDA-approved dose of enoxaparin, 30 mg given twice daily. The primary efficacy outcome was a composite of symptomatic or asymptomatic deep vein thrombosis, pulmonary embolism, and death by any cause. The rate of the primary efficacy endpoint on apixaban was numerically similar to that observed with enoxaparin (9.0% vs. 8.9%, p=.064), but did not meet the pre-specified statistical criteria for non-inferiority compared to enoxaparin. The actual enoxaparin VTE rate of 8.9 percent was lower than the expected VTE rate of 16 percent seen in previous similar clinical trials, resulting in an inability to demonstrate non-inferiority.

In ADVANCE-1, there were no unexpected findings in adverse events for apixaban compared to enoxaparin. The major bleeding event rate for apixaban was numerically lower, but was not significantly lower, than enoxaparin (0.7% vs. 1.4%, p=.053). The composite rate of clinically relevant non-major bleeding and major bleeding was significantly less in patients who received apixaban than those who received enoxaparin (2.9% vs. 4.3%, p =.034).

Full results of the ADVANCE-1 trial have been submitted to the American Society of Hematology Meeting (ASH) for presentation in December.

ADVANCE-1 results confirm the characteristics of apixaban as reported previously in phase II studies. The companies are considering further studies with different protocols in preventing VTE in knee surgery and will not submit the U.S. filing for VTE prevention in the 2nd half of 2009, as previously communicated. The results of ADVANCE -1 do not necessitate any changes in protocols of any other ongoing apixaban studies. Programs directed towards prevention of VTE including EMEA registrational studies, treatment of VTE, and in the prevention of stroke in atrial fibrillation continue as planned.

“Bristol-Myers Squibb and Pfizer remain enthusiastic and committed to the clinical development program for apixaban,” said Jack Lawrence, vice president, Research and Development, Bristol-Myers Squibb. “Bristol-Myers Squibb and Pfizer anticipate that the results of APPRAISE-1 being presented at ESC will provide important insight into the potential use of apixaban for the secondary prevention of cardiovascular events in patients with acute coronary syndrome, which affects an estimated 2.7 million people around the world every year.”

About the Apixaban Clinical Program

Apixaban, an oral, factor Xa inhibitor in a new class of agents that have shown therapeutic potential to prevent and treat blood clots, is currently being explored in the EXPANSE clinical trial program which includes eight Phase III clinical studies involving approximately 45,000 patients worldwide. The ADVANCE-2 and 3 trials are investigating the safety and efficacy of apixaban 2.5 mg twice daily compared to enoxaparin 40 mg once daily in patients undergoing major orthopedic surgery. The ADOPT study is investigating apixaban for one month compared to standard of care (enoxaparin 40 mg once daily 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 III trials studying the prevention of stroke and other thromboembolic events in patients with atrial fibrillation (AF). The AF program consists of two trials. The ARISTOTLE trial is investigating apixaban compared to warfarin in approximately 15,000 patients with atrial fibrillation. The AVERROES trial is investigating apixaban compared to aspirin in approximately 5,600 patients with atrial fibrillation who are ineligible for vitamin K antagonists (VKA) treatment or haven’t tolerated previous VKA treatment.

The VTE treatment program consists of two trials. The AMPLIFY trial is a 6-month trial investigating apixaban compared to enoxaparin plus warfarin in approximately 4,800 patients with acute DVT or PE. The AMPLIFY-EXT trial is a 12-month trial investigating apixaban compared to placebo for extended treatment to prevent recurrent VTE in approximately 2,400 patients who have completed 6 to 12 months of treatment for DVT or PE.

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. For more information visit 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 the research, development and commercialization of products. 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 clinical trials described in this release will support a regulatory filing or that the product will receive regulatory approval. There can be no assurance that if approved, the product described in this release will be commercially successful. Forward-looking statements in the 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, 2007, its Quarterly Reports on Form 10-Q, and 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 Forward-Looking Statement

The information contained in this release is as of August 26, 2008. 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 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 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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