APPRAISE-2 Study with Investigational Compound Apixaban in Acute Coronary Syndrome Discontinued

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PRINCETON, N.J. & NEW YORK--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer (NYSE: PFE) today reported that the companies have discontinued the Phase 3 APPRAISE-2 clinical trial in patients with recent Acute Coronary Syndrome (ACS) treated with apixaban or placebo in addition to mono or dual antiplatelet therapy. The study was stopped early based on the recommendation of an independent Data Monitoring Committee (DMC). There was clear evidence of a clinically important increase in bleeding among patients randomized to apixaban. This increase in bleeding was not offset by clinically meaningful reductions in ischemic events.

The APPRAISE-2 Trial (Apixaban for Prevention of Acute Ischemic Events – 2), one of nine clinical trials evaluating apixaban in patients at risk of ischemic events, was designed to include approximately 10,800 patients with a recent Acute Coronary Syndrome. Patients were randomized to apixaban 5 mg twice daily or placebo. The study was conducted in 40 countries and was coordinated by Duke Clinical Research Institute in the U.S. and Uppsala Clinical Research Center in Sweden.

The companies have informed the APPRAISE-2 investigators, ethics review boards and regulatory health authorities of the decision to stop the study. Enrollment will be stopped and patients will be taken off of the study drug. The lead investigators will complete a full

evaluation of the available data set and the results will be made public.

"We remain committed to the development of apixaban in other patient populations," said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. "We are focused on the rolling submission of data for the prevention of stroke in patients with atrial fibrillation who are expected or demonstrated to be unsuitable for treatment with warfarin to the Food and Drug Administration and the application to the European Medicines Agency for venous thromboembolism (VTE) prevention. Other ongoing studies investigating apixaban in different patient populations are being monitored by independent data monitoring committees and are continuing."

"Our recommendation to discontinue APPRAISE-2 concerns only the population of high-risk ACS patients receiving anti-platelet therapy enrolled in APPRAISE-2," said Robert Harrington, M.D., Duke Clinical Research Institute, and co-chair of the APPRAISE-2 Steering Committee. "Recent Phase 3 clinical trials of apixaban have demonstrated promising results in patients with VTE and atrial fibrillation. We look forward to reviewing the complete APPRAISE-2 data, when it is available; to better understand this apparently different risk profile in patients with ACS."

Based on the APPRAISE-2 recommendation, the DMC for APPRAISE Japan, a Phase 2 study in ACS patients, has also recommended discontinuation for APPRAISE Japan.

About the Apixaban Clinical Trial Program

Apixaban, which is currently being developed by Bristol-Myers Squibb and Pfizer, is an investigational oral factor Xa inhibitor, a new class of agents being studied for the prevention and treatment of blood clots. Apixaban 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 eight completed or ongoing, randomized, double-blind Phase 3 trials.

The apixaban Phase 3 trial program is evaluating the prevention of venous thromboembolism, prevention of stroke and other thromboembolic events in patients with atrial fibrillation and the treatment of venous thromboembolism.

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 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 www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

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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 apixaban will receive regulatory approval or, if approved, that it will become a commercially successful product. There is also no guarantee that other ongoing clinical trials of apixaban will proceed unchanged. 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, 2009, 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 18, 2010. 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 potential indications for a product candidate, 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 are being or may be filed for such indications as well as their decisions regarding labeling and other matters that could affect their 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, 2009 and in its reports on Form 10-Q and Form 8-K.

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