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ELIQUIS® (apixaban) Approved In Europe For Preventing Venous Thromboembolism After Elective Hip Or Knee Replacement

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First approval for ELIQUIS, a new oral direct Factor Xa inhibitor

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(BUSINESS WIRE)--The European Commission has approved ELIQUIS® in the 27 countries of the European Union (EU) for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. This decision marks the first approval for ELIQUIS®, a new oral direct Factor Xa inhibitor being developed by the alliance of Bristol-Myers Squibb Company and Pfizer Inc.

“Major orthopedic surgery, such as total knee replacement or total hip replacement, puts patients at a very high risk of developing VTE or pulmonary embolism. The absolute risk of deep vein thrombosis for these patients ranges from 40 to 60 percent when these patients do not receive preventive care,” said Michael Rud Lassen, M.D., Glostrup Hospital in Copenhagen, Denmark, and lead investigator for the Phase 3 orthopedic trials for ELIQUIS. “The approval of ELIQUIS gives European orthopedic surgeons a new option in VTE prevention that is more effective than the current standard of care, enoxaparin 40 mg once daily, and importantly, without increasing bleeding.”

The approval of ELIQUIS is based on the ADVANCE-2 and ADVANCE-3 clinical trials, part of the EXPANSE clinical trial program. In these trials, ELIQUIS given orally twice daily demonstrated superior efficacy versus enoxaparin 40 mg given once daily by injection in the prevention of VTE in total knee and total hip replacement, and did not increase the risk of bleeding versus enoxaparin. These trials randomized over 8,000 patients and assessed the safety and efficacy of ELIQUIS compared to enoxaparin. The primary efficacy endpoint of ADVANCE-2 and ADVANCE-3, which studied patients undergoing elective total knee or hip replacement, respectively, was defined as the composite of asymptomatic and symptomatic deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE), and death from any cause during study treatment. The principal safety measure in the trials was the composite of major and clinically relevant non-major bleeding.

ELIQUIS is the only oral anticoagulant with a 12- to 24-hour post surgery initiation window, which may help physicians to observe and stabilize post-surgical patients before beginning treatment. ELIQUIS is dosed 2.5 mg twice daily, requires no routine platelet or liver monitoring, and requires no dose adjustment in indicated patients. In patients undergoing hip replacement surgery, the recommended duration of treatment is 32 to 38 days. In patients undergoing knee replacement surgery, the recommended duration of treatment is 10 to 14 days.

“As the first ELIQUIS approval worldwide, today marks an important milestone for the Bristol-Myers Squibb/Pfizer Alliance,” said Beatrice Cazala, senior vice president, Commercial Operations, and president, Global Commercialization, Europe and Emerging Markets, Bristol-Myers Squibb. “We are confident that our shared resources and leadership in the treatment of cardiovascular disease will help make the European launch a success and continue to bring value to the development of ELIQUIS.”

“The approval of ELIQUIS provides a new oral option for patients in the EU undergoing elective hip or knee replacement surgery, where the risk of bleeding is a significant concern,” said Olivier Brandicourt, president and general manager, Primary Care, Pfizer Inc. “We are excited to bring this new agent to market in Europe and provide orthopedic surgeons with an option that will help them to prevent VTE in patients undergoing elective total knee or total hip replacement surgery.”

About Venous Thromboembolism

VTE encompasses two serious conditions: DVT, a blood clot in a vein, usually in the leg that partially or totally blocks the flow of blood; and PE, a blood clot blocking one or more vessels in the lungs. DVT causes multiple symptoms including pain, swelling and redness and, more importantly, can progress to PE, which carries the risk of sudden death.

About the ELIQUIS® Clinical Trial Program

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 the ADVANCE trials.

In addition to prevention of VTE in orthopedic surgery, ELIQUIS is being investigated in Phase 3 trials for the treatment of VTE, the prevention of VTE in hospitalized acutely ill medical patients and the prevention of stroke and other thromboembolic events in patients with atrial fibrillation.

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.

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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.

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 launch of apixaban will be a success or that apixaban will become a commercially successful product. There is also no guarantee that any potential additional indications for apixaban will receive regulatory approval. 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 May 20, 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 ELIQUIS (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, 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 ELIQUIS 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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