U.S. FDA Acknowledges Receipt of Resubmission of the New Drug Application for Investigational Compound Dapagliflozin for the Treatment of Type 2 Diabetes

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WILMINGTON, Del. & PRINCETON, N.J.--(BUSINESS WIRE)--AstraZeneca (NYSE: AZN) and Bristol-Myers Squibb Company (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the New Drug Application (NDA) resubmission for investigational drug dapagliflozin for the treatment of adults with type 2 diabetes. The FDA assigned a new Prescription Drug User Fee Act (PDUFA) goal date of Jan. 11, 2014.

The dapagliflozin Phase 2/3 clinical development program included more than 12,000 adult patients with diabetes (more than 8,000 patients received dapagliflozin) in 26 clinical trials. In response to the FDA’s January 2012 complete response letter requesting additional data to allow a better assessment of the benefit-risk profile of dapagliflozin, the NDA resubmission includes several new studies and additional long-term data (up to four years’ duration) from previously submitted studies, resulting in an overall increase in patient-years exposure to dapagliflozin of more than 50 percent.

Dapagliflozin, an investigational compound, is a selective and reversible inhibitor of sodium-glucose cotransporter 2 (SGLT2), which works independently of insulin. It is currently approved for the treatment of type 2 diabetes in the European Union, Australia, Brazil, Mexico and New Zealand.

About SGLT2 Inhibition

The kidney plays an important role in maintaining normal glucose balance by filtering and reabsorbing glucose from circulation. SGLT2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for approximately 90 percent of glucose reabsorption. In patients with type 2 diabetes, the capacity of the kidney to reabsorb glucose is increased by approximately 20 percent, further exacerbating the hyperglycemia associated with the disease. Selective inhibition of SGLT2 reduces the reabsorption of excess glucose and enables its removal via the urine.

About Diabetes

In 2012, diabetes was estimated to affect more than 370 million people worldwide. The prevalence of diabetes is projected to reach more than 550 million by 2030. Type 2 diabetes accounts for approximately 90% to 95% of all cases of diagnosed diabetes in adults. Type 2 diabetes is a chronic disease characterized by insulin resistance and dysfunction of beta cells in the pancreas, leading to elevated glucose levels. Over time, this sustained hyperglycemia contributes to further progression of the disease. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen.

AstraZeneca/Bristol-Myers Squibb Diabetes Alliance

Dedicated to addressing the global burden of diabetes by advancing individualized patient care, AstraZeneca and Bristol-Myers Squibb are working in collaboration to research, develop and commercialize a versatile portfolio of innovative treatment options for diabetes and related metabolic disorders that aim to provide treatment effects beyond glucose control. Find out more about the Alliance and our commitment to meeting the needs of health care professionals and people with diabetes at www.astrazeneca.com or www.bms.com.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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 prevalent over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

AstraZeneca Cautionary Statement Regarding Forward-Looking Statements

In order, among other things, to utilize the ‘safe harbor’ provisions of the US Private Securities Litigation Reform Act 1995,
we are providing the following cautionary statement: This press release contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward looking statements reflect knowledge and information available at the date of preparation of this press release and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of patents, marketing exclusivity or trademarks, or the risk of failure to obtain patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delay in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure to manage a crisis; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; the risk of environmental liabilities; the risks associated with conducting business in emerging markets; the risk of reputational damage; the risk of product counterfeiting; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programs; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; and the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation. Nothing in this press release should be construed as a profit forecast.

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 dapagliflozin will receive regulatory approval in the U.S. or, if approved, that it will become commercially successful. There is also no guarantee that the FDA will make a regulatory decision within the time frame described in this release. 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, 2012, 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.

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