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FDA Advisory Committee Recommends the Investigational SGLT2 Inhibitor Dapagliflozin for the Treatment of Type 2 Diabetes in Adults

AstraZeneca (NYSE:AZN) and Bristol-Myers Squibb Company (NYSE:BMY) announced on December 12, 2013 (US time) that the U.S. Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) voted 13-1 that the benefits of dapagliflozin use outweigh identified risks and support marketing of dapagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Attached from the following page is the press release made by AZN and BMY for your information.

Collaboration among Ono , AZN , BMY

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President, Representative Director, and CEO:Gyo Sagara) and AstraZeneca K.K. (Osaka, President and Representative Director: Gabriel Baertschi) concluded an agreement to co-promote dapagliflozin on December 3, 2013.
AZN simultaneously entered into an agreement with BMY granting AZN exclusive rights to commercialise dapagliflozin in Japan once approved.
BMY and AZN will supply dapagliflozin and Ono will be responsible for its distribution.
Ono and AZN will jointly detail dapagliflozin to healthcare professionals in Japan.
Bristol-Myers K.K. (Tokyo, Japan, Representative Director and President: Davide Piras) submitted a new drug application for dapagliflozin in Japan in March 2013 to the Ministry of Health, Labour and Welfare.

FDA Advisory Committee Recommends the Investigational SGLT2 Inhibitor Dapagliflozin for the Treatment of Type 2 Diabetes in Adults

(WILMINGTON, Del., and PRINCETON, NJ, Dec. 12, 2013) – AstraZeneca (NYSE: AZN) and Bristol-Myers Squibb Company (NYSE: BMY) today announced the U.S. Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) voted 13-1 that the benefits of dapagliflozin use outweigh identified risks and support marketing of dapagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The Advisory Committee also voted 10-4 that the data provided sufficient evidence that dapagliflozin, relative to comparators, has an acceptable cardiovascular risk profile.

The FDA is not bound by the Advisory Committee's recommendation but takes its advice into consideration when reviewing the application for an investigational agent. The Prescription Drug User Fee Act (PDUFA) goal date for dapagliflozin is Jan. 11, 2014.

Dapagliflozin is being reviewed by the FDA for use as monotherapy, and in combination with other antidiabetic agents, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It is a selective and reversible inhibitor of sodium-glucose cotransporter 2 (SGLT2) that works independently of insulin to help remove excess glucose from the body. Dapagliflozin, an investigational compound in the U.S., was the first SGLT2 inhibitor to be approved anywhere in the world. Dapagliflozin is currently approved under the trade name FORXIGA™ for the treatment of adults with type 2 diabetes, along with diet and exercise, in 38 countries, including the European Union and Australia.

The EMDAC was provided with data from the extensive dapagliflozin global clinical development program included as part of the New Drug Application (NDA) and resubmission. In response to the FDA's Jan. 2012 complete response letter, the NDA resubmission included 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 as compared to exposure in the original NDA. The resubmission included

data from the dapagliflozin Phase II/III clinical development program, which included more than 11,000 adult patients with diabetes (approximately 6,000 patients received dapagliflozin) in 24 clinical trials.

Patient populations examined covered the range of diabetes progression, including drug-naïve patients, patients inadequately controlled on oral therapies and patients on insulin-based regimens. The program also provided significant experience in elderly patients, patients with a history of cardiovascular (CV) disease, overweight and obese patients, patients with poorly controlled hypertension and patients with mild to moderate renal impairment. In accordance with FDA guidelines, the NDA resubmission also included data assessing the CV safety of dapagliflozin in adults with type 2 diabetes. Additionally, the DECLARE study is being conducted in patients with type 2 diabetes to determine the effect of dapagliflozin, when added to the patients' current anti-diabetes therapy, on the risk of CV events, such as CV death, myocardial infarction or ischemic stroke, compared with placebo. The randomized, double-blind, placebo-controlled study of more than 17,000 patients initiated enrollment in April 2013 and has an anticipated completion date of 2019.

About Type 2 Diabetes

Diabetes is estimated to affect 26 million people in the U.S. and more than 382 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035. Type 2 diabetes accounts for approximately 90-95 percent of all cases of diagnosed diabetes. Type 2 diabetes is a chronic disease characterized by several pathophysiologic defects, including insulin resistance and dysfunction of pancreatic beta cells, 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.

About SGLT2 Inhibition

The kidney plays an important role in maintaining normal glucose balance, in part by filtering and subsequently reabsorbing glucose back into circulation. SGLT2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for the majority of glucose reabsorption in the kidneys. In patients with type 2 diabetes, the capacity of the kidney to

reabsorb glucose is increased by approximately 20-30 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 the 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 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 prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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 a commercially successful product. 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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