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FDA ACKNOWLEDGES RECEIPT OF RESUBMISSION OF THE NEW DRUG APPLICATION FOR INVESTIGATIONAL COMPOUND DAPAGLIFLOZIN FOR THE TREATMENT OF TYPE 2 DIABETES

Fredag, 26 juli 2013

AstraZeneca and Bristol-Myers Squibb Company 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 goal date of January 11 2014.

The dapagliflozin Phase II/III 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.

– ENDS –

NOTES TO EDITORS

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% of glucose reabsorption. In patients with type 2 diabetes, the capacity of the kidney to reabsorb glucose is increased by approximately 20%, 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.

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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 commercialise 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 http://www.astrazeneca.com or www.bms.com.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation 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 http://www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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