US FDA APPROVES EXPANDED INDICATION FOR BRILINTA TO INCLUDE LONG-TERM USE IN PATIENTS WITH A HISTORY OF HEART ATTACK

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved BRILINTA® (ticagrelor) tablets at a new 60mg dose to be used in patients with a history of heart attack beyond the first year. With this expanded indication, BRILINTA is now approved to reduce the rate of cardiovascular death, myocardial infarction (MI, also known as heart attack) and stroke in patients with acute coronary syndrome (ACS) or a history of MI.

BRILINTA is an oral antiplatelet treatment that works by inhibiting platelet activation and was first approved by the FDA in July 2011 on the basis of data from the PLATO study. For at least the first 12 months following ACS, it is superior to clopidogrel and is the first and only oral antiplatelet to demonstrate superior reductions in cardiovascular death. BRILINTA also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS. In the management of ACS, the recommended maintenance dose of BRILINTA is 90mg twice daily during the first year after the ACS event. After one year, patients with a history of heart attack can now be treated with 60mg twice daily.

Elisabeth Björk, Vice President, Head of Cardiovascular and Metabolic Diseases, Global Medicines Development, AstraZeneca, said: "We know that patients remain at risk beyond the first year after their heart attack. Today's approval is an important milestone that underscores the role BRILINTA can play in reducing the risk of a subsequent cardiovascular event for patients both in the acute setting and in the longer term."

The expanded indication for BRILINTA has been approved under FDA Priority Review, a designation granted to medicines that the FDA determines have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease. The approval is based on the PEGASUS TIMI-54 study1, a large-scale outcomes trial involving more than 21,000 patients. PEGASUS TIMI-54 investigated ticagrelor tablets plus low-dose aspirin, compared to placebo plus low dose aspirin, for the long-term prevention of cardiovascular death, heart attack and stroke in patients who had experienced a heart attack one to three years prior to study enrollment.

Marc Sabatine, MD, MPH, Chairman, Thrombolysis in Myocardial Infarction (TIMI) Study Group, Brigham and Women's Hospital, Boston, MA, USA and lead investigator for PEGASUS-TIMI 54, said: "The PEGASUS-TIMI 54 trial demonstrated that the addition of ticagrelor to low-dose aspirin in patients with a prior heart attack significantly reduced the risk of dying from cardiovascular causes, having another heart attack, or having a stroke. While it's important that physicians tailor their treatment approach for each patient, these data speak to the clinically important benefit that can be gained when adding ticagrelor to the current standard therapy in a patient population at increased risk for recurrent cardiovascular events in the long-term."

BRILINTA has been approved in over 100 countries and is included in 12 major ACS treatment guidelines globally. In the American Heart Association (AHA)/American College of Cardiology (ACC) 2014 NSTE-ACS Guideline, BRILINTA is preferred over clopidogrel for the maintenance treatment in NSTE-ACS patients (Class IIa) and is recommended as a treatment option in the management of NSTE-ACS patients (Class I).

The new BRILINTA 60mg tablet is expected to be available in pharmacies by the end of September 2015.

1 Bonaca MP, Bhatt DL, Cohen M, et al. Long-term use of ticagrelor in patients with prior myocardial infarction. N Engl J Med. 2015;372:1791-800

About BRILINTA

BRILINTA is an oral antiplatelet treatment for acute coronary syndrome (ACS). BRILINTA is a direct-acting P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). BRILINTA works by inhibiting platelet activation and has been shown to reduce the rate of thrombotic CV events, such as a heart attack or CV death, in patients with ACS.

About PEGASUS-TIMI 54

PEGASUS-TIMI 54 (PrEvention with TicaGrelor of SecondAry Thrombotic Events in High-RiSk Patients with Prior AcUte Coronary Syndrome - Thrombolysis In Myocardial Infarction Study Group) is AstraZeneca's largest outcomes trial with more than 21,000 patients from over 1,100 sites in 31 countries. The study assessed BRILINTA® (ticagrelor) tablets at either 60mg twice daily or 90mg twice daily plus once daily low-dose aspirin for the secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to study start. The primary efficacy endpoint was a composite of cardiovascular (CV) death, myocardial infarction (MI) or stroke. The study was conducted in collaboration with the Thrombolysis in Myocardial Infarction (TIMI) Study Group from Brigham and Women's Hospital (Boston, MA, USA).

The PEGASUS-TIMI 54 study is part of the PARTHENON programme. Further ongoing PARTHENON studies are assessing ticagrelor for the prevention of cardiovascular events in patients with peripheral artery disease, ischaemic stroke or transient ischaemic attack, and in patients with diabetes and coronary atherosclerosis.

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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

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