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FDA priority review designation for AZ's Brilinta

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The US Food and Drug Administration (FDA) has accepted and granted Priority Review designation to AstraZeneca's Brilinta (ticagrelor) supplemental new drug application (sNDA) to treat patients with a history of heart attack.

The sNDA is based on the results of the PEGASUS-TIMI 54 study, a large-scale outcomes trial in more than 21,000 patients that investigated ticagrelor tablets plus low dose aspirin, compared to placebo plus low dose aspirin, for the chronic secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to study enrolment. The Prescription Drug User Fee Act goal date will be in the third quarter of 2015.

Elisabeth BjÃ¶rk, vice president, head of Cardiovascular and Metabolic Diseases, Global Medicines Development, said "Recent research has shown that one in five patients will have a further heart attack, stroke or cardiovascular death in the subsequent three years following a heart attack, even if they are event free after the first 12 months."

"There is a clear need for treatment options beyond the current standard of care of aspirin for the long-term prevention of atherothrombotic cardiovascular events in patients with a history of myocardial infarction. Today's milestone reinforces the importance of investigating clinical questions that address unmet patient need and we look forward to working with the FDA as they review our submission."

A Priority Review designation is granted to medicines that the FDA determines have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease.

The PEGASUS TIMI-54 study was presented during the opening late-breaking clinical trial session of the American College of Cardiology's 64th annual Scientific Session and Expo on March 14, 2015, and was also simultaneously published in the

New England Journal of Medicine.

PEGASUS-TIMI 54 is part of AstraZeneca's PARTHENON programme. The PLATO study, involving over 18,000 patients, was the first study in the programme and is the basis on which ticagrelor has been approved in over 100 countries and included in 12 major ACS treatment guidelines globally.

Further ongoing PARTHENON studies are assessing ticagrelor for the prevention of cardiovascular events in patients with peripheral arterial disease, ischaemic stroke or transient ischaemic attack, and in patients with diabetes and coronary atherosclerosis.

Brilinta is a direct-acting, selective and reversibly binding P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). Brilinta works by inhibiting platelet activation.

Brilinta (90mg) is indicated to reduce the rate of thrombotic CV events in patients with ACS (unstable angina [UA], non-ST-elevation myocardial infarction [NSTEMI], or ST-elevation myocardial infarction [STEMI]). Brilinta has been shown to reduce the rate of a combined end point of CV death, MI, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with percutaneous coronary intervention, it also reduces the rate of stent thrombosis.

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 one of AstraZeneca's largest ever outcomes trials with more than 21,000 patients from over 1,100 sites in 31 countries in Europe, the Americas, Africa and Australia/Asia.

The study assessed Brilinta (ticagrelor) tablets at either 60mg twice daily or 90mg twice daily plus 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. It was conducted in collaboration with the Thrombolysis in Myocardial Infarction (TIMI) Study Group from Brigham and Women's Hospital (Boston, MA, USA).

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.