BRILIQUE (TICAGRELOR) POSITIVE EU CHMP OPINION

BRILIQUE (TICAGRELOR) RECEIVES POSITIVE EUROPEAN UNION CHMP OPINION FOR EXTENDED TREATMENT OF PATIENTS with a history of heart attack

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of BRILIQUE (ticagrelor) 60mg for the treatment of patients with a history of heart attack and at high risk of having a further atherothrombotic event. The opinion states that, treatment may be started as continuation therapy after an initial one**l**year treatment with dual anti platelet therapy.

BRILIQUE 90mg is currently approved in the EU to reduce the rate of cardiovascular death, myocardial infarction (MI, also known as heart attack) and stroke in patients with acute coronary syndrome (ACS).

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are very pleased with today's positive opinion from the CHMP. Evidence shows that patients continue to be at risk of experiencing a subsequent cardiovascular event beyond the first year after their heart attack and we strongly believe in the role BRILIQUE can play in reducing this risk for patients both in the acute setting and in the longer term."

Commenting on the positive opinion, Professor Philippe Gabriel Steg, Professor of Cardiology at the University of Paris, said: "The potential approval of 60 mg dose for ticagrelor (BRILIQUE) in Europe provides an opportunity for prolonged protection against cardiovascular events in patients at highest risk with an optimised risk/benefit ratio."

The positive CHMP opinion was based on the results from the PEGASUS TIMI-54 study1, a large-scale outcomes trial involving more than 21,000 patients, presented at American Cardiology Congress (ACC) in March 2015. PEGASUS TIMI-54 investigated ticagrelor tablets plus low-dose aspirin, compared to placebo plus low dose aspirin, for the long-term prevention of cardiovascular (CV) death, heart attack and stroke in patients who had experienced a heart attack one to three years prior to study enrollment. The study showed that BRILIQUE significantly reduced the primary endpoint of CV death, MI or stroke compared to placebo. The rates at 3 years were 7.77% in the ticagrelor 60mg arm and 9.04% in the placebo arm.

The CHMP's positive opinion on BRILIQUE will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland, Norway and Liechtenstein. If approved, BRILIQUE will be the first oral antiplatelet approved in these markets for the long term treatment of patients with a history of heart attack.

Today's announcement follows the approval on 3 September 2015 of BRILINTA (ticagrelor) 60mg by the US Food and Drug Administration, to be used in patients with a history of heart attack beyond the first year.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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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