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New ESC Guidelines Recommend BRILIQUE (ticagrelor) in all Moderate-To-High Risk Patients With Non-ST Elevation Acute Coronary Syndromes

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- This release is not intended for US media

Ticagrelor Recommended for Medically & Invasively Managed

NSTE-ACS Patients Regardless of Prior Treatment with Clopidogrel

AstraZeneca today announced BRILIQUE (ticagrelor), a new oral antiplatelet medicine, received a Class I recommendation (level of evidence B) from the European Society of Cardiology (ESC) in the revised "Guidelines for Management of Acute Coronary Syndromes (ACS) in patients presenting without persistent ST-segment elevation."

In these 2011 guidelines, ticagrelor is recommended for all non-ST elevation ACS patients at moderate-to-high risk of ischaemic events, regardless of initial treatment strategy and including those pre-treated with clopidogrel (which should be discontinued when ticagrelor is commenced) (Class 1, level of evidence B). In addition, the guidelines recommend ticagrelor be considered for initiation or resumption following coronary artery bypass graft (CABG) surgery as soon as it is considered safe (Class IIa, level of evidence B).

"The inclusion of ticagrelor in the new NSTE-ACS ESC guidelines is another important step toward improving ACS patient care in the EU," said Professor Lars Wallentin, co-primary investigator of the PLATO study and Professor of Cardiology and Research Director at the Uppsala University, Sweden.

The ESC guidelines as well as marketing authorisation in the EU for ticagrelor were based on a review of the ticagrelor clinical programme, including results from PLATO (A Study of PLATelet Inhibition and Patient Outcomes), which established the superiority of ticagrelor over clopidogrel, and showed that treating 54 ACS patients with ticagrelor instead of clopidogrel for one year prevented one atherothrombotic event and treating 91 patients prevented one cardiovascular (CV) death, with no increase in overall major/fatal bleeding over the course of one year of treatment (11.6% for ticagrelor versus 11.2% for clopidogrel, p=0.43). However, non-CABG major bleeding was more common with ticagrelor versus clopidogrel (4.5% vs. 3.8%, p=0.03).

On 6 December 2010, the European Commission granted marketing authorisation to ticagrelor, co-administered with acetylsalicylic acid (ASA) (maintenance dose 75-150mg daily), for the prevention of atherothrombotic events in adult patients with ACS (unstable angina, NSTEMI, or STEMI), including patients managed medically and those who are managed with percutaneous coronary intervention (PCI) or CABG. This decision followed advance incorporation of the medicine into ESC's 2010 Guidelines for Myocardial Revascularisation [http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-revasc-FT.pdf] in August.

These updates to the 2011 Guidelines for Management of Acute Coronary Syndromes (ACS) in patients presenting without persistent ST-segment elevation [http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/Guidelines-NSTE-ACS-FT.pdf] have been featured in an ESC press release [http://www.escardio.org/about /press/press-releases/esc11-paris/Pages/guidelines-acute-coronary-syndromes.aspx] and presented at an ESC press conference on Monday, 29th August in Paris, France, while simultaneously being published in the European Heart Journal. Ticagrelor is also recommended for treatment of ACS in the Canadian Cardiovascular Society Guidelines [http://download.journals.elsevierhealth.com/pdfs/journals/0828-282X/PIIS0828282X10000310.pdf] .

NOTES TO EDITORS

ABOUT ESC GUIDELINES

Class I indicates "evidence and/or general agreement that a given treatment or procedure is bene?cial, useful, effective," while level of evidence B signifies that this recommendation was based upon a single randomised clinical trial. Class IIa indicates the "weight of evidence/opinion is in favour of usefulness/efficacy."

ABOUT PLATO PLATO was a large (18,624 patients in 43 countries), head-to-head patient outcomes study of ticagrelor versus clopidogrel, both given in combination with aspirin and other standard therapy, designed to establish whether ticagrelor could achieve a clinically meaningful reduction in CV end points in ACS patients, above and beyond those afforded by clopidogrel.

The study demonstrated that treatment with BRILIQUE led to a greater reduction in the primary end point - a composite of CV death, MI, or stroke - compared to patients who received clopidogrel [9.8% vs. 11.7% at 12 months, 1.9% absolute risk reduction (ARR), 16% relative risk reduction (RRR), 95% CI, 0.77 to 0.92, p<0.001]. The difference in treatments was driven by CV death and MI with no difference in stroke. In PLATO, the absolute difference in treatment benefit versus clopidogrel was seen at 30 days and the Kaplan-Meier survival curves continued to diverge throughout the 12-month treatment period.

The study also demonstrated that treatment with BRILIQUE for 12 months was associated with a 21 percent RRR in CV death (4% vs. 5.1%, 1.1% ARR, p=0.001) and a 16 percent RRR in MI compared to clopidogrel at 12 months (5.8% vs. 6.9%, 1.1% ARR, p<0.005).

The results of this analysis formed the basis of the recommendation in all of the approved BRILIQUE labels that patients taking BRILIQUE should also take a low-maintenance dose of aspirin daily, unless specifically contraindicated.

About BRILIQUE (ticagrelor tablets)

BRILIQUE is an oral antiplatelet treatment for ACS. BRILIQUE is a direct-acting P2Y12 receptor antagonist in a new chemical class called cyclopentyltriazolopyrimidines (CPTPs). BRILIQUE is the first reversibly-binding oral ADP receptor antagonist to be approved for use in ACS.

BRILINTA has now been approved in 43 countries, including in the European Union under the trade name BRILIQUE and in the United States, Canada, Brazil, Malaysia and Macau under the trade name BRILINTA. BRILINTA is currently under regulatory review in 49 countries, including Russia, India and China.

BRILINTA and BRILIQUE are trademarks of the AstraZeneca group of companies. For detailed information regarding BRILINTA / BRILIQUE, please refer to the local Summary of Product Characteristics.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US $33.3 billion in 2010. For more information please visit: http://www.astrazeneca.com

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