

Brilinta (ticagrelor) Tablets Clinical Update

Clinical Update: Approved in the US to Reduce the Risk of a First Heart Attack or Stroke in High-Risk Patients with Coronary Artery Disease.

FDA approval date: May 28, 2020

Brilinta (ticagrelor) is an oral, reversible, direct-acting P2Y₁₂ receptor antagonist that works by inhibiting platelet activation. Brilinta, together with aspirin, has been shown to significantly reduce the risk of MACE defined as myocardial infarction (MI, heart attack), stroke or CV death, in patients with ACS or a history of MI. Brilinta, co-administered with aspirin is indicated for the prevention of atherothrombotic events in adult patients with ACS, or for patients with a history of MI and a high risk of developing an atherothrombotic event.

AstraZeneca's Brilinta (ticagrelor) has been approved in the US to reduce the risk of a first heart attack or stroke in high-risk patients with coronary artery disease (CAD), the most common type of heart disease. The approval by the US Food and Drug Administration (FDA) was based on positive results from the Phase III THEMIS trial. The trial showed a statistically significant reduction in the primary composite endpoint of major adverse cardiovascular (CV) events at 36 months with aspirin plus Brilinta 60mg versus aspirin alone in patients with CAD and type-2 diabetes (T2D) at high-risk of a first heart attack or stroke. The primary composite endpoint was driven by a reduction in heart attack and stroke. The safety profile for Brilinta was consistent with the known profile of the medicine with an increased risk of bleeding events observed. The data from the THEMIS trial and the THEMIS-PCI sub-analysis were published in The New England Journal of Medicine and The Lancet respectively. AstraZeneca also recently announced the high-level results from the Phase III THALES trial that showed aspirin plus Brilinta 90mg reduced the risk of the composite of stroke and death at 30 days after an acute ischaemic stroke or transient ischaemic attack, compared to aspirin alone.

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