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PEGAGUS-TIMI 54 Study With Ticagrelor Meets Primary End Point

Michael O'Riordan | January 14, 2015

WILMINGTON, DE — A large-scale morbidity and mortality trial testing ticagrelor (*Brilinta*, AstraZeneca) on top of low-dose aspirin therapy showed the drug significantly reduced the risk of major adverse cardiovascular events in high-risk patients with a history of MI, according to an announcement from the company today[1].

The Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin-Thrombolysis in Myocardial Infarction 54 (PEGASUS-TIMI 54) study, which is a randomized, double-blind, placebo-controlled trial testing twice-daily doses of ticagrelor 60 mg and 90 mg, met its primary end point, said AstraZeneca in a press release announcing the topline results.

PEGAGUS-TIMI 54, which is led by Dr Marc Sabatine (Brigham and Women's Hospital, Boston, MA), enrolled more than 21 000 patients who had an MI within the past 1 to 3 years and who had at least one other cardiovascular risk factor. All patients were currently treated with aspirin 75 mg to 150 mg and were randomized in a 1:1:1 fashion to ticagrelor 60 mg twice daily, ticagrelor 90 mg twice daily, or placebo. The primary end point of the study is a composite of cardiovascular death, nonfatal MI, or nonfatal stroke.

The company did not provide any details except to say the study was positive and that a preliminary analysis did not reveal any unexpected safety issues. The investigators are continuing to analyze the data, and full results of the trial are expected to be presented at a cardiology meeting in 2015.

Ticagrelor is not currently approved for secondary prevention but is approved for the reduction of cardiovascular events in the acute coronary syndrome setting. That approval was based on the PLATO trial. As reported by **heartwire** , the PLATO study attracted its share of controversy and was criticized for a number of reasons, including apparent geographic discrepancies, such as a trend toward worse outcomes with ticagrelor vs clopidogrel at North American sites, the timing of deaths in the study, site monitoring, MI definitions, and other issues.

These concerns even attracted the US Department of Justice, which initiated an investigation into the PLATO trial. The investigation closed in August 2014 and did not result in any actions from the government, however.

References

1. AstraZeneca. PEGASUS-TIMI 54 study of Brilinta meets primary end point in both 60-mg and 90-mg doses [press release]. January 14, 2015. Available here.

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