www.medscape.com

FDA Favorably Views Cangrelor in PCI for CAD Patients Ahead of Panel Meeting

Deborah Brauser | April 13, 2015

BETHESDA, MD — The injectable antiplatelet agent cangrelor (the Medicines Company, Parsippany, NJ) may be one step closer to approval for use as an adjunct to PCI for reducing thrombotic events in patients with CAD, should the panel vote in concert with the briefing documents released today by the Cardiovascular and Renal Drugs Advisory Committee of the US Food and Drug Administration (FDA)[1]

Although official vote by the committee won't come until the end of Wednesday, FDA reviewers are recommending that cangrelor be approved "in patients in whom treatment with an oral P2Y12 platelet inhibitor prior to PCI is not feasible and when glycoprotein IIb/IIIa–receptor antagonists are not anticipated to be used." This is in contrast to last year's vote.

In February 2014, the advisory committee voted 7 to 2 that cangrelor should not be approved because the risk/benefit profile was not sufficient enough. In addition, although the large CHAMPION-PHOENIX trial showed positive results, the previous CHAMPION-PLATFORM and CHAMPION-PCI trials were negative and weighed into the decision making of some of the panel members.

After requesting and receiving further sensitivity analyses and a more simplified application letter, the reviewers now state that PHOENIX is sufficient enough as a stand-alone trial to warrant approval.

"The benefit of cangrelor compared with clopidogrel is small, but the risk is smaller," write the reviewers. "Treating 171 patients prevents one clinically meaningful periprocedural MI. In comparison, treating 1106 patients causes one GUSTO severe bleed, a safety factor of ~6.5-fold. Using a less severe bleed to assess benefit risk, such as a GUSTO moderate or TIMI minor bleed, still favors the use of cangrelor."

Last year, the advisory committee also recommended unanimously that cangrelor not be approved as a "bridging" therapy for patients with stents who stop oral P2Y12 inhibitors because of surgery. The Medicines Company is no longer seeking to market the medication for that indication.

References

1. Food and Drug Administration. FDA briefing document for the Cardiovascular and Renal Drugs Advisory Committee. April 13, 2015. Available here.

Cite this article: FDA Favorably Views Cangrelor in PCI for CAD Patients Ahead of Panel Meeting . *Medscape*. Apr 13, 2015.