

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Washington DC/Silver Spring, Maryland
8727 Colesville Road, Silver Spring, Maryland
May 19, 2011**

Questions to the Advisory Committee

1. Discuss your interpretation of the primary efficacy results from ACCORD-Lipid, specifically as they relate to Trilipix's indication for coadministration with a statin.

2. In the subgroup of women from ACCORD-Lipid, the incidence of MACE in patients randomized to simvastatin plus placebo was 6.6% compared to 9.1% in patients randomized to simvastatin plus fenofibrate (interaction p-value 0.01 vs. men).

Discuss your interpretation of this subgroup finding, specifically as it relates to Trilipix's indication for coadministration with a statin.

3. In the subgroup of patients from ACCORD-Lipid with baseline levels of TG \geq 204 mg/dl and HDL-C \leq 34 mg/dl, the incidence of MACE in patients randomized to simvastatin plus placebo was 17.3% compared to 12.4% in patients randomized to simvastatin plus fenofibrate (interaction p-value 0.06 vs. all others).

Discuss your interpretation of this subgroup finding, specifically as it relates to Trilipix's indication for coadministration with a statin.

4. Discuss the safety profile of fenofibrate/fenofibric acid, specifically as it relates to Trilipix's indication for coadministration with a statin.

5. Discuss the benefit-risk profile of Trilipix when used in combination with a statin to reduce TG and increase HDL-C in patients with mixed dyslipidemia and CHD or a CHD equivalent who are on optimal statin therapy to achieve their LDL-C goal.

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6. Taking into account all relevant data and levels of evidence:

- A. Should FDA require the conduct of a clinical trial designed to test the hypothesis that, in high-risk men and women at LDL-C goal on a statin with residually high TG and low HDL-C, add-on therapy with Trilipix versus placebo significantly lowers the risk for MACE.

VOTE: Yes or No and provide rationale for your recommendation

- B. Which action do you recommend FDA take regarding Trilipix's indication for coadministration with a statin:

1. Allow continued marketing of Trilipix's indication for coadministration with a statin without revision of the labeling.
2. Withdraw approval of Trilipix's indication for coadministration with a statin.
3. Allow continued marketing of Trilipix's indication for coadministration with a statin with revision of the labeling to incorporate the principal findings from ACCORD-Lipid.

VOTE: 1, 2, or 3 and provide rationale for your recommendation.