

SHARP FDA Advisory Committee Meeting 2nd November 2011: Panel recommendations and praise for SHARP

In parallel with the publication of the main SHARP results in the Lancet, the study results have been submitted to a variety of healthcare regulatory agencies around world. Following an extensive review of the data, the United States Food and Drug Administration (FDA) convened a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee in Washington DC on 2nd November 2011 to discuss the study results and their implications for clinical practice. The Advisory Committee included eminent clinicians and statisticians, and also patient and consumer representatives.

SHARP principal investigator Professor Colin Baigent presented the study rationale, design and results, and the SHARP Steering Committee Chairman Professor Sir Rory Collins spoke about the public health implications of the study results. Presentations were also made by Merck & Co., the manufacturers of ezetimibe plus simvastatin, and the FDA Clinical Reviewer.

At the end of the day-long open meeting, the Advisory Committee voted 16 to 0 in favour of approving the use of ezetimibe 10mg plus simvastatin 20mg in patients with pre-dialysis kidney disease, but after much discussion did not endorse its use in dialysis patients. The FDA will now consider this advice before determining whether the labelling of the treatment should be changed in some (or all) kidney patients.

The Advisory Committee had high praise for the SHARP study with comments including:

- “A well run and organised study that went to lots of effort to get good data on the target group. The results are truly robust.”
- “A wonderful addition to the care of CKD patients. It is going to change care.”
- “An important study, it was extremely well designed.”
- “The way in which this study has been conducted and communicated is of tremendous value. This is an exceptionally well-designed and well done study.”
- “This is an amazing day. You have a study that is independent, transparent, hypothesis-driven and achieved its end points.”

These comments are testimony to the hard work of all the participants and staff involved with SHARP around the world. The Advisory Committee’s endorsement of the study results and the use of ezetimibe 10mg plus simvastatin 20mg in patients with CKD is an important step towards improving the health of kidney patients world-wide.

The presentations and other material related to this meeting can also be viewed on the FDA website:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs>