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HEART STUDY GEARS UP FOR ANALYSIS

Data analysis plans for HPS2-THRIVE have been published on the study's website, prior to un-blinding of the main efficacy results.

HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) has randomized 25,673 people who have some form of heart or other vascular disease. It is investigating whether ER niacin/Iaropiprant 2g daily can reduce the risk of heart attacks, strokes, coronary deaths and other vascular complications.

After median follow-up of about 4 years, the study closed as planned in October 2012. The investigators anticipate reporting the full results in early 2013.

The study is sponsored by the University of Oxford and funded by Merck, Sharp & Dohme Co. Inc. Details of the primary, secondary and tertiary outcomes and the planned methods of analysis can be found at: www.ctsu.ox.ac.uk/~thrive/. Participants are taking simvastatin 40mg or ezetimibe/simvastatin 10/40mg as background therapy.

The Clinical Trial Service Unit (CTSU) at Oxford University has designed the HPS2-THRIVE study and is responsible for coordinating it and analysing its results, independently of the funders (MSD). The CTSU is well known for running huge international studies, including the ground-breaking Heart Protection Study which showed that a third of all heart attacks and strokes can be safely avoided in people at risk of vascular disease by using statins to lower bad 'LDL' cholesterol. The CTSU also showed that more intensive lowering of LDL cholesterol with statins safely produces extra benefits .

Large randomized studies have previously shown that lowering LDL cholesterol by 1 mmol/L (40 mg/dL) for 4-5 years with statin therapy cuts the risks of heart attacks and strokes by about a fifth, and recent studies suggest that more intensive LDL-lowering can produce extra benefits. But, despite the use of statins, the risk of heart attacks, strokes and other vascular complications among people who have vascular disease remains high.

Niacin's effects include raising good cholesterol (HDL) and further lowering bad (LDL) cholesterol even in people already on statins and it is hoped that these changes will translate into benefits for patients. Previous studies have shown that people with high blood levels of HDL cholesterol tend to have fewer heart attacks or coronary deaths. However, there is limited evidence of any benefits with the drugs that are currently available to raise HDL cholesterol including niacin. The use of niacin has been limited by side-effects, with "flushing" being the most common. Laropiprant is a prostaglandin D receptor antagonist which reduces flushing and has been combined with extended-release (ER) niacin in a single tablet which is being tested in HPS2-THRIVE.

Professor Jane Armitage of Oxford University, the chief investigator of HPS2-THRIVE, said: "HPS2-THRIVE has randomized over 25,000 participants and has a good chance of being able to detect plausible reductions in the rate of major vascular events (such as heart attacks and strokes) that ER niacin/laropiprant might produce."

Dr Martin Landray, one of the co-principal investigators, said: "HPS2-THRIVE will provide reliable information on the clinical benefits of ER niacin/laropiprant. Despite being used for over 50 years to treat dyslipidaemia it remains uncertain whether niacin – when added to statin therapy – can reduce clinical outcomes like heart attacks and strokes. HPS2-THRIVE should provide a robust answer to this important clinical question."

Dr Richard Haynes said: "Niacin causes a number of side-effects. HPS2-THRIVE should be able to determine whether any cardiovascular benefits outweigh these side-effects in patients at high risk of vascular disease treated with statins."

End.

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