A new game-changing therapy in preventing heart disease? Regeneron and Sanofi think so.

By ACSH Staff — September 2, 2014

In what may be the most important development in the management of coronary heart disease (CHD) since the discovery of statins, clinical trials of an antibody called alirocumab which is being developed by Regeneron and Sanofi have produced some astounding results in reducing LDL, the bad type of cholesterol.

Not only has the drug done this in spectacular fashion, but the reduction of LDL has translated into a significant reduction in cardiovascular (CV) events.

A series of four Phase III trials called Odyssey, the drug a monoclonal antibody has met or exceeded the endpoints of the trials. Since the drug is an antibody, it must be given by injection in this case one every two weeks.

For example, at 24 weeks, there was a 61% reduction in LDL levels in the alirocumab group as compared to a 1% increase in the placebo group at 24 weeks. This number was essentially identical at 52 weeks.

Among patients at high CV risk, the endpoint of reducing LDL cholesterol (LDLC) to either 70 mg/dL or 100 mg/dL depending on the magnitude of risk at the start of the trial was achieved by 81 percent of patients.

Although a larger trial of 18,000 patients designed to measure a different endpoint a decrease in cardiovascular events is ongoing, clinicians were able to obtain these data from the smaller trials: The rate of CV events (cardiac death, myocardial infarction, stroke, and unstable angina requiring hospitalization) was reduced by over 50 percent in patients who got the drug, compared with placebo.

More details on the alirocumab trials can be found here [1].
It is also informative to read Derek Lowe’s report [2] on earlier clinical trial data on alirocumab (from October 2013). He also discusses why the LDL-lowering strategy is not entirely understood, based on the failure of another drug, Zetia, to protect people from CV events, even though it lowered LDL as it was designed to do.


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