

Abbott Release Statement on AIM-HIGH Study

Final results were presented from the AIM-HIGH study, a National Heart, Lung and Blood Institute (NHLBI) study. The study was designed to test whether raising HDL "good" cholesterol by adding Niaspan to simvastatin would provide an additional 25 percent reduction in cardiovascular outcomes in patients with established cardiovascular disease and well-controlled LDL "bad" cholesterol levels. The study was stopped early following an interim analysis in May and found that combination therapy did not result in an additional reduction in cardiovascular events beyond treatment with simvastatin in this patient population with well-controlled LDL cholesterol and non-HDL-cholesterol (a measure of all plaque causing particles). In response, Abbott issued the following statement:

The AIM-HIGH study answered an important question about the benefits of additional lipid treatment for the specific type of patients enrolled in the study – those with stable established cardiovascular disease whose lipids were well-controlled at or near primary and secondary lipid goals at the start of the study. Current treatment guidelines would not have recommended that these patients receive additional lipid therapy.

According to the National Cholesterol Education Program (NCEP) guidelines, LDL cholesterol is the primary target of lipid therapy. For patients at high cardiovascular risk, such as those enrolled in the AIM-HIGH study, guidelines recommend an optional LDL goal of 70 mg/dL or less. Additionally, non-HDL cholesterol of 100 mg/dL or less is the secondary goal of lipid treatment for high-risk patients when triglycerides are elevated (greater than 200 mg/dL) and after LDL goal is reached. Ninety-four percent of patients in the AIM-HIGH study were already taking statins, with most of this group taking statins for more than a year, many for more than five years. In these patients, although baseline HDL cholesterol levels were low (35 mg/dL), they had LDL cholesterol levels of 71 mg/dL, non-HDL cholesterol levels of 106 mg/dL and triglycerides of 161 mg/dL.

The results from the AIM-HIGH study should not be applied beyond the patient population studied. The 3,414 patients in the AIM-HIGH study represent a small percentage of high-risk patients who reach their guideline-recommended lipid treatment goals and are not representative of the typical patient being treated for lipid disorders in clinical practice today.

"Niaspan remains an important treatment option to help patients reach their lipid treatment goals, many of whom require multiple medications to do so. Even when looking only at the high-risk patient group evaluated in the AIM-HIGH study, epidemiologic data tell us that in clinical practice more than three-quarters of these patients do not reach their recommended goals for lipid therapy," said John Leonard, M.D., senior vice president, Global Pharmaceutical Research and Development, Abbott. "Physicians should consider each patient's cardiovascular profile and the NCEP treatment guidelines when evaluating a patient for potential additional treatment with lipid lowering medicines such as Niaspan."

In the interim data, an unexpected imbalance in ischemic stroke events in patients who received Niaspan and simvastatin as compared to simvastatin was identified. The final data showed that the difference in ischemic stroke events between the two study arms was not statistically significant. Previous studies, meta-analyses and post-marketing safety data also did not show any stroke safety signals related to niacin or Niaspan.

The findings from the AIM-HIGH study were presented at the American Heart Association Scientific Sessions 2011 and were simultaneously published online in the *New England Journal of Medicine*.

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