Statement from the American Diabetes Association Related to ACCORD Trial Announcement

ACCORD data raises concerns; Group advises patients with diabetes to maintain good control of blood glucose and talk to their doctor.

Alexandria, VA (Vocus) February 6, 2008 -- In response to today’s announcement by the National Heart, Lung, and Blood Institute, which sponsors the ACCORD (Action to Control Cardiovascular Risk in Diabetes) Trial to stop the intensive blood glucose (sugar) control sub-study in ACCORD due to safety concerns, the American Diabetes Association strongly encourages people with diabetes not to alter their course of treatment without first consulting with their health care team. The American Diabetes Association continues to encourage good control of blood glucose for the management of diabetes and its complications.

The ACCORD trial randomized patients with diabetes and vascular disease or multiple cardiovascular risk factors to an intensive treatment program targeting normal blood glucose values and an A1C less than 6 percent or a standard treatment program with an A1C between 7 percent and 7.9 percent. The intensive participants in ACCORD are now being switched to the standard treatment program because of an increased death rate in the intensive treatment program (14 deaths per 1000 patients per year versus 11 per 1000 patients per year in the standard treatment program; a difference of 0.3 death per 100 patients per year).

The American Diabetes Association continues to advise people with diabetes to strive for an A1C (a measure of long-term blood glucose control) of less than 7 percent. Recent data indicates that more than half of the population with diabetes in the U.S. have an A1C less than 7 percent and this overall level of glucose control appears to be of great benefit rather than harm.

The importance of glucose control in diabetes is firmly established. Evidence from the landmark Diabetes Control and Complications Trial (DCCT), and the U.K. Prospective Diabetes Study (UKPDS) show that improved glucose control to a level of approximately 7 percent reduces the complications of diabetes dramatically.

The Association’s treatment guidelines also state that treatment should be tailored to the individual patient and that for some people with diabetes, intensive glucose control may not be warranted. Of note, the American Diabetes Association (in its Standards of Medical Care) states: “Less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, children, individuals with comorbid conditions, and those with longstanding diabetes and minimal or stable microvascular complications.”

This recent announcement by ACCORD investigators suggests that very intensive glucose lowering treatment aimed at normalizing blood glucose (A1C<6%) may be detrimental, at least in middle-aged and older adults with vascular disease or multiple risk factors for vascular disease. The exact reason for the increased death rates with intensive treatment that occurred in ACCORD are not yet known. However, an analysis of the ACCORD data indicates that the detrimental effect of intensive therapy was not due to hypoglycemia or any specific combination of drug therapies.

The American Diabetes Association looks forward to more analysis of the data from ACCORD, as well as other ongoing studies that may shed more light on this issue. However, at this time, the American Diabetes
Association advises people with diabetes who have existing cardiovascular disease (CVD), or multiple CVD risk factors, to consult with their health care team about their treatment goals and to ensure that their blood pressure and cholesterol are appropriately managed.

The American Diabetes Association is the nation’s premier voluntary health organization supporting diabetes research, information and advocacy. Founded in 1940, the Association's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The Association's commitment to research is reflected through its scientific meetings; education and provider recognition programs; and its Research Foundation and Nationwide Research Program, which fund breakthrough studies looking into the cure, prevention, and treatment of diabetes and its complications. Visit the American Diabetes Association at www.diabetes.org or call 1-800-DIABETES (1-800-342-2383).

Note to editors: Information from the NHLBI can be found at www.nhlbi.nih.gov

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