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## **GLAXOSMITHKLINE RESPONDS TO FINDINGS IN ACCORD STUDY**

The following is a GlaxoSmithKline statement regarding the ACCORD study:

These could be important findings if they can shed more light on how we improve the management of patients with diabetes. We certainly need to know a lot more about these data and what they mean, given the complexity of the disease and its management. Importantly for patients currently on treatment, The National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) has said that none of the medicines in the study appear to be the cause of the increased risk. The study is continuing, and patients will continue to receive Avandia (rosiglitazone maleate) and all other diabetes medicines; however, the goal for glucose control will be adjusted. Patients will be moved from intensive management to standard glucose control.

More specifically:

- These findings appear to raise questions about how aggressively blood sugar should be reduced in managing diabetes among the high risk patients in the ACCORD study. The increased risk does not appear to be caused by any single medicine or combination of medicines. The same drugs are used in both groups of patients who are either managed aggressively or to standard blood sugar control; yet the small increase of events is seen in the group who are aggressively managed.
- The NHLBI specifically reviewed rosiglitazone to determine if there was any link between rosiglitazone with the increased risk and have "found no link."
- Importantly, the ACCORD study is not being stopped, and patients are not being taken off any medicine. The changes will be to what level patients' blood sugar is managed. Rosiglitazone and the other medicines will continue to be used within the study.
- Previously, a small (150 patients), 2-year pilot study that pre-dated TZDs suggested a similar trend towards increased risk in cardiovascular events. In this study, published in 1997 in the Archives of Internal Medicine, a trend towards more cardiovascular events was seen in the intensive glucose treatment arm.

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## EDITOR'S NOTE

The NHLBI press release states: "Extensive analyses by ACCORD researchers have not determined a specific cause for the increased deaths among the intensive treatment group. Based on analyses conducted to date, there is no evidence that any medication or combination of medications is responsible.

"Because of the recent concerns with rosiglitazone, our extensive analysis included a specific review to determine whether there was any link between this particular medication and the increased deaths. We found no link," said William T. Friedewald, M.D., ACCORD Steering Committee Chair and Clinical Professor of Medicine and Public Health at Columbia University."

For more information from the NHLBI, please visit  
<http://www.nhlbi.nih.gov/health/prof/heart/other/accord/index.htm>

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