

The largest ever study of Diabetes shows Intensive Glucose Control Reduces Serious Complications

"ADVANCE results go beyond existing evidence"

Mumbai, Maharashtra, June 13, 2008 /[India PRwire](#)/ -- New results from the world's largest ever study of diabetes treatments show that intensive blood glucose (sugar) control using modified release gliclazide and other drugs as required, protects patients against serious complications of the disease. In particular, intensive treatment reduces the risk of kidney disease by one-fifth. Presented today at the American Diabetes Association and published in the *New England Journal of Medicine*, the results of ADVANCE (Action in Diabetes and Vascular Disease) show that this intensive treatment strategy has the potential to benefit millions of diabetic patients worldwide.

Diabetes mellitus is one of the greatest threats to the health of populations worldwide. India has the highest number of people with diabetes in the world (40.9 million), with around 250 million people globally living with the condition. This number is estimated to rise to 380 million in 2025, when the largest increases in diabetes prevalence will take place in developing countries.

Chief investigator of the study, Professor Stephen MacMahon, Principal Director of The George Institute, Australia said "We are facing a global epidemic of diabetes. The ADVANCE results go beyond existing evidence as we have now shown that reducing the haemoglobin A1c level (a marker of blood glucose control) to 6.5% is a safe and effective way to reduce serious complications, particularly the risk of kidney disease, one of the most serious and disabling consequences of diabetes, leading to death in one in five people with diabetes."

"Hypoglycemia (low blood sugar) was uncommon in the ADVANCE study, although as expected it was more frequent among those receiving intensive treatment," pointed out Study Director, Associate Professor Anushka Patel from The George Institute. "These findings reinforce that blood glucose lowering in diabetes is safe and has an important role to play in the prevention of serious complications."

"Moreover, in contrast to the recently halted ACCORD study, there was no evidence whatsoever of any increased risk of death among those receiving intensive treatment in ADVANCE."

"The ADVANCE study has provided vital information to India about the effects of managing blood glucose levels in diabetes. This is important as India is estimated to have over 40 million persons with diabetes - the highest population of diabetes in the world," said Professor Nikhil Tandon, National Co-ordinator for ADVANCE, at the All India Institute of Medical Sciences.

ADVANCE was initiated and designed by physicians at Australia's George Institute for International Health and involved a group of independent medical researchers from 20 countries worldwide. The study involved 11,140 patients with type 2 diabetes who were treated and followed up for five years. The study aimed to reduce levels of haemoglobin A1c to 6.5% or below. Intensive treatment included the sulfonylurea, modified-release gliclazide, for all patients and other drugs as required to achieve the haemoglobin target.

The major findings of ADVANCE show that intensive blood glucose lowering treatment:

- Safely controlled blood glucose to a mean HbA1c level of 6.5%
- Significantly reduced the overall risk of serious diabetes complications (by 10%), with a one-fifth reduction in kidney disease (21%) and 30% reduction in the development of proteinuria, a well established marker of increased cardiovascular risk.
- Achieved a positive trend towards reduction in the risk of cardiovascular death (12%), although not statistically significant.

"Today, it is clear that the prevention of major vascular complications of diabetes requires a multi-factorial approach addressing all modifiable risk factors" concluded Professor John Chalmers, chairman of the study

management group, “among which an intensive glucose control plays an important role, in particular in protecting the kidneys”.

The George Institute, India which was launched in 2007, is working to reduce the burden of disease caused by conditions such as diabetes. This new information in the management of diabetes is directly aligned with the Institute’s goal to identify practical new ways of addressing this serious health problem.

Notes to Editor

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ADVANCE was designed, conducted, monitored, analysed and reported by a collaborative medical research group supported by the Australian Government’s National Health and Medical Research Council after full peer review. The study was carried out independently of the industry sponsor and the Management Committee, whose membership did not include any industry representatives, had final responsibility for the reporting of results.

Confidence Intervals: Intensive control reduced the combined major macrovascular and microvascular endpoint (18.1% vs. 20.0%; hazard ratio (HR) 0.90, 95% confidence interval 0.82 to 0.98, $p=0.013$). Major microvascular events were reduced (9.4% vs. 10.9%; HR 0.86 [0.77 to 0.97], $p=0.014$), primarily because of a reduction in nephropathy (4.1% vs. 5.2%; HR 0.79 [0.66 to 0.93], $p=0.006$), with no significant effect on retinopathy ($p>0.1$).

The first part of ADVANCE investigated the effects of intensive blood pressure lowering on outcome using a fixed combination of perindopril and indapamide. The results were published last year. Reference: ADVANCE Collaborative Group; Patel A, MacMahon S, Chalmers J, Neal B *et al.* Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): a randomised controlled trial. *Lancet* 2007; 370:829-40.

The George Institute for International Health is an internationally-recognised health research organisation, undertaking high impact research across a broad health landscape. It is a leader in the clinical trials, health policy and capacity-building areas. The Institute has a global network of top medical experts in a range of research fields as well as expertise in research design, project management and data and statistical analysis. With a respected voice among global policy makers, The Institute has attracted significant funding support from governments, philanthropic organisations and corporations. George Institute research is regularly published in the top tier of academic journals internationally.

The National Health & Medical Research Council of Australia is the Australian Government’s peak body for supporting health and medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research.

SERDIA is the Indian subsidiary of a research-based French multinational - the Servier Research Group.

Management committee and investigators of the ADVANCE trial:

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