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Landmark study shows 40% reduction in cardiovascular events and stroke

Study halted early due to superior outcomes

Dorval, Quebec, April 30, 2007 – New findings from the independent Jikei Heart Study, published in this week's issue of *The Lancet*¹, show that adding the blood pressure lowering medication ^{PR}Diovan* (valsartan) to conventional therapy produced a dramatic 39% reduction in cardiovascular events, including a 40% reduction in stroke. The superior benefits in the Diovan treatment group led to an early termination of this study, which involved more than 3,000 patients.

The Jikei Heart Study is the first controlled trial to assess the cardiovascular benefits of adding the angiotensin receptor blocker (ARB) Diovan to conventional therapy, compared to conventional therapy alone in a large Japanese population with high blood pressure, coronary heart disease and/or heart failure. Key events evaluated as part of the primary endpoint included heart attack, stroke and hospitalization for heart failure or angina pectoris.

In addition to its impact on overall cardiovascular events and stroke, Diovan demonstrated relative reductions of 65% in hospitalizations for angina pectoris (recurring acute chest pain) and 46% in hospitalizations for heart failure (a progressive disorder manifested by fluid congestion and weakening of the heart) compared to the other treatment group.¹ According to investigators, these benefits cannot be explained by a difference in blood pressure alone.¹ There were few adverse events (2.5% overall) with no significant difference in tolerability between treatment groups.

“The findings from the Jikei Heart Study are important for physicians who are trying to prevent their patients from long-term cardiovascular complications, such as stroke,” said Peter Lin, MD, CCFP, Primary Care Physician, Toronto, Ontario. “This study is relevant because it followed patients with existing conditions common in clinical practice. The results demonstrate that reducing blood pressure to target is important, but which medication we choose is also critical. It also complements previous evidence that adding Diovan to usual treatment for high blood pressure can also offer cardiovascular protection.”

More details on the trial

The Jikei Heart Study¹ was an investigator-initiated, multi-center, controlled clinical trial with a prospective randomized, open-label, blinded endpoint (PROBE) design. It was conducted by the Jikei University School of Medicine in Tokyo in 3,081 Japanese people aged 20 to 79 years with high blood pressure, ischemic heart disease or congestive heart failure. Patients were randomly assigned to one of two treatment arms: treatment with the angiotensin receptor blocker (ARB) Diovan or a non-ARB therapy (standard antihypertensive therapy excluding other ARBs). There were no significant differences in blood pressure or heart rate between the treatment groups.

Key events counted in the primary composite endpoint of cardiovascular mortality and morbidity (which measured an overall 39% reduction in events) were: new or recurrent stroke or transient

ischemic attack (a mini-stroke), hospitalization for congestive heart failure, or angina pectoris, heart attack, dissecting aortic aneurysm, lower limb arterial obstruction (blockages in the arteries in the lower body), doubling of serum creatinine (a measurement of kidney function), or transition to dialysis.

The study was conceived, designed, and conducted by an investigator-led steering committee, representing the Jikei Executive Committee and the hospitals involved with the trial. The study was funded by the Jikei University School of Medicine in Tokyo with an unrestricted grant from Novartis. Novartis had no role in study design, data collection, data analysis, data interpretation or writing of the report.

The conventional therapies in both groups included medications such as calcium channel blockers, ACE inhibitors, beta blockers, statin medications and/or diuretics.

Cardiovascular disease and stroke in Canada

Cardiovascular disease accounts for the death of more Canadians than any other disease. In 2002 (the latest year for which Statistics Canada has data), cardiovascular disease accounted for approximately 75,000 Canadian deaths: 54% of all cardiovascular deaths are due to coronary artery disease; 21% to stroke; 16% to other forms of heart disease such as problems with the electrical system of the heart, viral heart infections, and heart muscle disease, and the remaining 9% to vascular problems such as high blood pressure and hardening of the arteries.²

In Canada, stroke is the fourth most common cause of death. Between 40,000 to 50,000 Canadians suffer from a stroke each year, resulting in approximately 16,000 deaths. Of these sufferers, more than 40% are left with a moderate to severe impairment, while 10% are so severely disabled they require long-term care.³

Diovan

Approved in Canada in 1997, Diovan (valsartan) is a highly selective angiotensin II ATI receptor blocker (ARB), and is indicated in Canada for the treatment of mild to moderate essential hypertension and to reduce cardiovascular mortality in clinically stable patients with signs and symptoms of left ventricular dysfunction in conjunction with acute myocardial infarction when the use of an angiotensin-converting enzyme inhibitor (ACEI) is not appropriate. Diovan may be administered alone, or in combination with thiazide diuretics or as a fixed dose combination called Diovan-HCT.

Novartis is focused on improving the care of patients with high blood pressure and heart disease through world-class research and unprecedented public health initiatives. The Diovan clinical trial programme is one of the world's largest in cardiovascular research, involving approximately 50,000 patients. Completed Diovan trials include Val-HeFT in heart failure patients, VALUE in high risk patient populations, as well as VALIANT in patients following heart attack. Ongoing studies include NAVIGATOR in pre-diabetes patients at high risk for cardiovascular disease.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "can offer" or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Diovan or Diovan-HCT, or regarding potential future sales of these products. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan or Diovan-HCT to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan or Diovan-HCT will be approved for any additional indications or labelling in any other market. Nor can there be any guarantee regarding potential future sales of Diovan or Diovan-HCT. In particular, management's expectations regarding these products could be affected by, among other things, competition in general;

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About Novartis Canada

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. Novartis Pharmaceuticals Canada conducts hundreds of clinical trials across the country seeking new treatments for cardiovascular disease, diabetes, cancer, ophthalmology and organ transplantation. In 2006, the Company invested over \$69 million in research and development. Novartis Pharmaceuticals Canada Inc. employs more than 850 people in Canada and its headquarters are located in Dorval, Quebec. In addition to Novartis Pharmaceuticals Canada Inc., the Novartis Group in Canada consists of Novartis Animal Health Canada Inc., Novartis Consumer Health Canada Inc., (including Novartis Nutrition Corporation) CIBA Vision Canada Inc. and Sandoz Canada Inc. For further information about Novartis Canada, please consult <http://www.novartis.ca>.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

*Diovan is a registered trademark.

References

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