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Novartis Pharma Schweiz AG

Diovan (valsartan) significantly reduces risk of restenosis in patients after stent implantation

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Val-PREST Study provides further evidence of Diovan's protective effects in cardiovascular disease. Basel, London (ots-PRNewswire)- New research, presented at the 4th International Symposium on Angiotensin II Antagonism in London, shows that the highly selective angiotensin receptor blocker (ARB) Diovan (valsartan) significantly reduces the risk of restenosis in patients after stent implantation by 50% (p(0.005), and the need for re-intervention by 58% (p(0.005) in patients with coronary artery disease.¹ This is the first demonstration of a positive effect by systemic pharmacological intervention on restenosis rate after stent implantation. Dr Stefan Peters, lead investigator for Val-PREST2 (Valsartan for Prevention of Restenosis After Stenting of Type B2/C Lesions*) at the Dorothea Christiane Hospital, Erxleben, Quedlimburg, Germany, comments, "Restenosis (narrowing of a coronary artery that has been previously widened) remains a major limitation of balloon angioplasty and stenting procedures. This finding is important as the practical benefits for patients may include a reduced risk of myocardial infarction, reduction in the need for hospitalisation for further invasive stenting procedures, and improvements in quality of life." Val-PREST was a randomised, open-labelled, single-centre clinical trial involving 200 patients with coronary artery disease requiring coronary intervention.² Over a six-month treatment period, 99 patients received 80mg Diovan daily and 101 received open treatment (including beta blocker and/or ACE inhibitor); patients in both groups also received 100mg aspirin and 250mg ticlopidine for four weeks. Administration of Diovan 80mg led to a significant (p(0.005) reduction in the risk of restenosis: 20% of patients in the Diovan group experienced restenosis, compared to 40% in the open treatment group. Re-intervention was 12% in the Diovan group compared to 29% in the open treatment group. Diovan prevents the detrimental effects of angiotensin II at the AT1 receptor while preserving the beneficial effects through the unblocked AT2 receptor. Angiotensin II plays an important role in endothelial function. The endothelium (the single layer of flattened cells lining blood vessels) is crucial in the regulation of vascular tone, growth and structure. After arterial injury due to stenting, Diovan, by selectively blocking the AT1 receptor, may reduce vascular smooth muscle cell migration and proliferation within the endothelium and may consequently reduce in-stent restenosis. The results of Val-PREST add to the growing body of evidence that confirms the highly protective effect of Diovan across a variety of cardiovascular diseases. The recently presented landmark Val-HeFT study has already demonstrated cardio-protective benefits with Diovan in patients with heart failure, through proven reduced combined all-cause mortality and morbidity in patients also taking usual therapy. Diovan is now the only angiotensin II receptor blocker (ARB) to demonstrate this benefit in a large-scale trial in patients with heart failure.³ Diovan has also been shown to confer renal protection through reduced microalbuminuria,⁴ as well as demonstrating benefits through reduction of left ventricular dysfunction.⁵ In addition to these studies, Novartis is conducting three other major international trials to support the Diovan promise of prolonging and improving patients' lives across a variety of cardiovascular disease states by enrolling 35,000 patients in the largest clinical trial programme of any AT1 receptor blocking agent. VALIANT (post-myocardial infarction patients); VALUE (high-risk patients with hypertension); and ABCD-2V (involving adult type-2 diabetes patients with either normal or high blood pressure). Diovan is a well-established, highly selective angiotensin receptor blocker (ARB) and is recommended by the World Health Organisation (WHO) for first-line treatment of hypertension. Over three million patients world-wide currently take Diovan. Approved in more than 80 countries, Diovan is the fastest growing branded prescription antihypertensive in several markets including the US. Diovan achieved sales of 1.2 billion CHF in 2000. Novartis is to seek world-wide approvals for Diovan in the treatment of heart failure based on the positive findings of Val-HeFT. This press release contains forward looking statements which can be identified by the use of forward looking terminology such as "may include a reduced risk", "prevents", "may reduce", "conducting", "promise", "growing" or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned clinical trials will result in the commercialisation of any product in any market. Any such commercialisation can be affected by, amongst other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results. Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. 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*B2/C lesions as defined by the ACC/AHA classification are atherosclerotic lesions on the blood vessel wall that are of a complex nature (many factors determine the complexity of the lesions, e.g., if formed at an artery branch). These lesions often require surgical intervention through angioplasty to widen the narrowed artery.

References

- 1 Data presented at the 4th Angiotensin II Antagonism meeting, London, 3-5 April, 2001
- 2 Peters, S. Valsartan for prevention of restenosis after stenting of type B2/C lesions: the Val-PREST trial, Journal of Invasive Cardiology 2000;13(12):93-97
- 3 Data presented at the 73rd Scientific Sessions of the American Heart Association, New Orleans, 12-15 November, 2000
- 4 Muirhead N, et al. Valsartan (Diovan): effect on microalbuminuria in patients with type II diabetes and nephropathy. J Am Coll Cardiol 1999;33(Suppl A):299A.Abstract 872-5
- 5 Thurmann PA, et al. Influence of the angiotensin II antagonist valsartan on left ventricular hypertrophy in patients with essential hypertension. Circulation 1998;98:2037-42

General information about hypertension and Diovan is available at <http://www.hypertensionandhealth.com>

ots Originaltext: Novartis AG Internet: www.newsaktuell.ch Contact: Novartis International AG Novartis Communication CH-4002 Basel Switzerland Tel +41 61 324 2200 Fax +41 61 324 3300 Inter<http://www.novartis.com>

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