



Novartis International AG
Novartis Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

Eric Althoff
Novartis Pharma Communications
+41 61 324 6392 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 1408 (mobile)
john.gilardi@novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

New data reinforce powerful blood pressure-lowering efficacy with Diovan®/Co-Diovan® based regimens

New evidence of cardiovascular and metabolic benefits further underscores strength of Diovan in high-risk hypertension patients

Milan, Italy, June 20, 2005 – People with moderate to severe hypertension treated with a combination of Diovan® (valsartan) and the diuretic hydrochlorothiazide (HCTZ) benefited from superior blood pressure reductions over those treated with amlodipine, according to the VAST study presented at the 15th European Meeting on Hypertension.

In addition, further data presented at the meeting underscored the benefits of powerful blood pressure lowering and potential protective metabolic and cardiovascular effects with Diovan-based treatment regimens, both as monotherapy and in combination with the diuretic HCTZ.

Diovan, the No. 1 angiotensin II-receptor blocker (ARB) worldwide, is also available in a once-daily fixed-dose combination with HCTZ as Co-Diovan® (valsartan and HCTZ), a potent agent for the treatment of hypertension.

According to the VAST study, patients with moderate to severe hypertension treated with a combination of Diovan and HCTZ (160/25) benefited from superior blood pressure reductions over those treated with amlodipine 10mg.¹ In addition, two new analyses of the VALUE trial demonstrated that Diovan may reduce the development of heart failure² and the onset of type II diabetes³ in high-risk patients with hypertension when compared with amlodipine. These findings follow recent marketing authorizations throughout Europe for the use of Diovan as a potentially lifesaving treatment for people who have had a recent heart attack and to treat people with existing heart failure.

“We already know that valsartan provides effective blood pressure-lowering and heart-saving benefits to people who have had a heart attack or have heart failure. Now these new data add to our understanding of valsartan’s efficacy in people with even earlier forms of heart disease,” said Luis Ruilope, MD, Hospital 12 de Octubre of Madrid, Spain, the primary investigator of VAST and an investigator for VALUE. “Large-scale trials have repeatedly shown that most high-risk patients with hypertension require aggressive treatment, either with a powerful monotherapy or more often with an effective fixed-dose combination, to reach healthy blood pressure goals.”

The results of VAST and the new analyses of VALUE follow the mandate from experts and guidelines which emphasize the critical need for more aggressive initial management of hypertension. Although cardiovascular disease (CVD) can be treated or prevented, according to the World Health Organization (WHO), across the globe around 17 million people die of CVD-related events each year, for which hypertension is a major contributing factor. Also, alarmingly, of those patients with hypertension who are treated, nearly 7 out of 10 do not achieve the goal of 140/90 mmHg as recommended by treatment guidelines. Patients with moderate to severe hypertension ($\geq 160/100$ mmHg), such as those in VAST, are at four times greater risk for cardiovascular events than those with optimal blood pressure ($< 120/80$ mmHg). In a sub-study of VAST, a significantly greater proportion of patients treated with Diovan plus HCTZ 160/25 mg reached their blood pressure goal ($\leq 130/80$ mmHg, measured by ambulatory monitoring) versus amlodipine 10mg (60.8% Diovan + HCTZ 160/25 mg vs. 48.4% Diovan + HCTZ 160/12.5 mg vs. 50.9% amlodipine 10mg; $p < 0.05$ for Diovan + HCTZ 160/25 mg vs. amlodipine 10mg).⁴

“As demonstrated by one of the largest clinical trials programs in its class, Diovan provides a unique range of benefits to patients with cardiovascular disease,” said Joerg Reinhardt, Head of Development, Novartis Pharma AG. “We have shown benefit over amlodipine, both as an effective monotherapy, where we have shown benefit in both heart failure and new onset diabetes, and in combination with a diuretic. The overall program has shown Diovan to effectively help patients get to goal and maintain a healthy blood pressure while providing additional longer-term cardioprotective benefits.”

More on VAST Presented at European Meeting on Hypertension

VAST (Valsartan/HCTZ versus Amlodipine in STage II hypertensive patients with additional risk factors) was a multicenter, multinational, randomized, double-blind, active-controlled, parallel group, 24-week study designed to evaluate the efficacy of Diovan + HCTZ 160/12.5 mg, Diovan + HCTZ 160/25 mg and amlodipine 10 mg on systolic blood pressure in a broad population of 1,088 patients with moderate to severe high blood pressure and additional cardiovascular risk factors. Mean systolic blood pressure at baseline was 167 mmHg, 166 mmHg, 166 mmHg for Diovan + HCTZ 160/12.5 mg, Diovan + HCTZ 160/25 mg and amlodipine, respectively. The mean diastolic blood pressure at baseline was 94 mmHg, 93 mmHg and 94 mmHg respectively.

Diovan + HCTZ 160/25 mg demonstrated superior efficacy in reducing systolic blood pressure vs. amlodipine 10mg ($p < 0.05$). Mean changes in blood pressure were: -29.7 ± 0.7 mmHg, 27.1 ± 0.7 mmHg and 27.6 ± 0.7 mmHg for the Diovan + HCTZ 160/25 mg, Diovan + HCTZ 160/12.5 mg and amlodipine groups, respectively. The difference in diastolic blood pressure between the groups was not statistically significant. Both Diovan + HCTZ 160/25 mg and 160/12.5 mg compared with amlodipine 10mg had a significantly lower rate of treatment-related adverse events (15.4% and 13.9% respectively vs. 42.7%; $p < 0.05$).¹

More on VALUE Presented at European Meeting on Hypertension

The new analyses of VALUE (Valsartan Antihypertensive Long-Term Use Evaluation) trial presented documented that Diovan-based antihypertensive regimens provide patients with important cardiovascular and metabolically protective effects.

- One of these analyses suggested that patients taking Diovan experienced similar blood pressure reductions with significantly fewer heart failure events compared to patients taking amlodipine monotherapy ($p = 0.045$). There were no differences in effects on stroke, MI or the primary endpoint of cardiac morbidity and mortality observed between the two treatment regimens in this analysis.²
- The second analysis from the VALUE trial suggested that the Diovan-based regimen was associated with a significant 23% reduction in the development of type II diabetes in high-risk patients compared with the amlodipine-based regimen. This finding was more significant in those patients at highest risk for developing diabetes.³

About Diovan

Novartis remains on the forefront of cardiovascular medicine, through development of innovative products like Diovan, one of the most prescribed antihypertensives in the world today. Novartis recently announced the successful completion of the EU Mutual Recognition Procedure (MRP) in 14 countries for Diovan for the treatment of heart attack survivors and the completion of a type II variation application for the treatment of people with heart failure.

Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries and is the only agent in its class with the indication for the treatment of heart failure in patients who also take usual therapy including diuretics, digitalis and either beta blockers or ACE inhibitors, but not both and in people at risk of a recurrent heart attack or other serious outcomes such as cardiovascular mortality, hospitalization for heart failure, resuscitated cardiac arrest or stroke. For heart failure, more than 60 countries have granted this approval and for post-heart attack more than 50. Additional marketing authorization applications are pending both for the treatment of post-heart attack and heart failure.

Novartis is committed to improving research, especially in cardiovascular and metabolism care. The Diovan clinical trial program represents one part of this commitment, involving more than 50,000 patients across the cardiovascular continuum. Recently completed Diovan megatrials include VALUE in hypertension patients at high-risk for cardiovascular complications, VALIANT in post-heart attack patients and Val-HeFT in heart failure patients. Ongoing studies include NAVIGATOR, the largest outcomes trial ever conducted on the delay or prevention of cardiovascular events and type II diabetes in patients with impaired glucose tolerance.

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “are pending” or similar expressions, or by express or implied discussions regarding potential new indications or labeling and marketing approvals for Diovan or Co-Diovan or regarding potential future sales of Diovan or Co-Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan or Co-Diovan 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 Co-Diovan will be approved for any additional indications or labeling in any other market. Nor can there be any guarantee regarding potential future sales of Diovan or Co-Diovan. In particular, management's expectations regarding commercialization of Diovan or Co-Diovan could be affected by, among other things, additional analysis of Diovan or Co-Diovan clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; industry, government, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events, or otherwise.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 81,400 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

#

Contacts:

Eric Althoff

Novartis Pharma Communications

+41 61 324 6392 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

References:

¹ Ruilope L, et al. Fixed-Dose Valsartan + Hydrochlorothiazide Combination Therapy Compared With Amlodipine Monotherapy In Hypertensive Patients With Additional Cardiovascular Risk Factors: The VAST Study. *Clinical Therapeutics* 2005 27:578-88.

² Julius S et al. VALUE Study: Outcomes In 7080 Patients Treated With Monotherapy. Presented June 19 at ESH 2005.

³ Kjeldsen SE, et al. Effects of Valsartan Preventing the Development of Type 2 Diabetes in High Risk Hypertensive Patients: Analysis from the VALUE Trial. Presented June 18 at ESH 2005.

⁴ Ruilope L et al. 24-Hour Ambulatory Blood-Pressure Effects of Valsartan + Hydrochlorothiazide Combinations Compared with Amlodipine in Hypertensive Patients at Increased Cardiovascular Risk. *Blood Pressure Monitoring* 2005 10:85-91.