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Novartis receives EU marketing authorization for Diovan® to treat people with heart failure

- *Leading antihypertensive is the only agent of its kind indicated to treat both heart attack survivors and people with heart failure*
- *Diovan provides a new treatment option for more than 4.5 million Europeans with heart failure*

Basel, June 13, 2005 — Novartis announced today that it has successfully completed an EU type 2 variation procedure in 14 countries for Diovan® (valsartan) for the treatment of people with heart failure. Diovan, a powerful antihypertensive agent, is now indicated as a potentially life-saving therapy for people with symptomatic heart failure when an ACE inhibitor can not be used, or as add-on therapy to ACE inhibitors when beta blockers can not be used. Diovan provides a new treatment option for the more than 4.5 million people with heart failure in the countries that are covered by this variation procedure.¹

This approval comes shortly after Novartis successfully completed an EU Mutual Recognition Procedure (MRP) for Diovan to treat heart attack survivors, making it the only agent in its class (angiotensin receptor blocker or ARB) indicated to treat hypertension, heart attack survivors and people with heart failure.

“Having an agent with a broad range of indications is particularly useful for clinicians because in the ‘real world’ many causes of cardiovascular disease overlap and one illness predisposes a person for another. Using a lesser number of drugs in patients like this is a good thing for both clinician and patient alike.” said Professor Tognoni, key investigator from Val-HeFT.

Heart failure occurs when the heart, after becoming damaged by a heart attack, high blood pressure or other conditions, loses its ability to pump enough blood through the body. Nearly eight million people suffer from heart failure and 600,000 new cases are reported every year in the EU.¹

“Physicians clearly need new treatments for heart failure, since almost two out of five² European heart failure patients are currently not receiving optimal therapy,” said Joerg Reinhardt, Head of Development, Novartis Pharma AG. “Diovan has demonstrated its versatility across a spectrum of cardiovascular conditions: high blood pressure, the aftermath of a recent heart attack and now heart failure. We remain committed to developing the full potential of this agent to help us bring the best treatment to people who need cardiovascular care.”

The new heart failure indication is based on data from Val-HeFT (Valsartan Heart Failure Trial). This trial demonstrated that Diovan reduced combined mortality and morbidity by 13.2% in heart failure patients also taking standard therapy, including a striking 33% reduction in mortality in heart failure patients not taking ACE inhibitors.

Heart failure develops slowly, often over years, as the heart gradually loses its pumping ability and works less efficiently, eventually leading to death. Heart failure is a debilitating condition that affects a patient's quality of life and life expectancy. While patients can make changes to their diet and physical activity, they will nevertheless require sustained drug treatment to improve the symptoms and outcomes associated with this condition.

New EU approval based on landmark Val-HeFT trial

With this authorization, Diovan will shortly be indicated in the following countries: Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, and Sweden. Upon granting of national marketing authorizations by these EU countries, Diovan will be approved in nearly 80 countries to treat people with heart failure. It was the first drug in its class indicated to treat heart failure, based on the positive findings of Val-HeFT. Val-HeFT examined 5,010 patients in 302 centers in 16 countries and compared the effects of Diovan vs. placebo in heart failure patients who also took usual treatments individually prescribed by their doctors, including ACE inhibitors, beta blockers, diuretics, or digitalis. It showed that Diovan significantly reduced combined heart failure mortality and morbidity by 13.2% and reduced hospitalization for heart failure by 27.5% versus placebo in patients also taking their individually prescribed heart failure drugs. In patients who were not prescribed ACE inhibitors, Diovan reduced mortality by 33% and mortality/morbidity by 44%.

Other findings from Val-HeFT showed that Diovan improves the signs and symptoms of heart failure, ejection fraction (a measure of the severity of the disease), NYHA functional class (a measure of disease progression) and positively affects several prognostic markers for poor outcomes, including brain natriuretic peptide (BNP), norepinephrine (NE)³, and aldosterone.⁴ A sub-study also demonstrated that atrial fibrillation occurrence further worsens the prognosis in patients with HF. Adding Diovan to prescribed therapy (93% ACE inhibitors, 35% beta blockers) significantly reduced the incidence of atrial fibrillation by nearly 35%⁵.

In addition, Diovan was also the first agent in its class to be approved for heart attack survivors based on the VALIANT (VALsartan In Acute myocardial iNfarcTion) trial, one of the largest long-term studies ever conducted in people who have survived a heart attack. VALIANT demonstrated that Diovan improved survival and reduced cardiovascular events in high risk patients following a heart attack. Diovan is the only cardiovascular agent ever demonstrated by a head-to-head trial to have matched the proven benefits of an ACE inhibitor in these patients.

About Diovan

The most prescribed ARB globally and one of the fastest-growing high blood pressure drugs on the market today, Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries and in more than 65 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. In the US and Switzerland, among other countries, Diovan is indicated for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. Diovan is also indicated in more than 50 countries to treat patients who have survived a heart attack.

This new indication for Diovan is for the treatment of people with symptomatic heart failure when ACE inhibitors can not be used, or as add-on therapy to ACE inhibitors when beta blockers can not be used.

Novartis is focused on improving the care of patients with high blood pressure and heart disease through world-class research. The Diovan clinical trial program, one of the largest in the world, represents an impressive research commitment across the cardiovascular continuum, involving approximately 50,000 patients. In addition to Val-HeFT and VALIANT, recently completed Diovan trials include VALUE in high blood pressure patients at risk for cardiovascular complications. Ongoing studies include the NAVIGATOR trial, the largest outcomes trial ever conducted on the prevention of cardiovascular disease and type 2 diabetes in patients with impaired glucose tolerance.

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “will be” or similar expressions, or by express or implied discussions regarding potential new indications or labeling and marketing approvals for Diovan or regarding potential future sales of Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with 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 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. In particular, management's expectations regarding commercialization of Diovan could be affected by, among other things, additional analysis of 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>.

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References

¹ Based on US prevalence and incidence rates applied to EU population figures.

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³ Anand I et al. Changes in Brain Natriuretic Peptide and Norepinephrine Over Time are Related to Subsequent Mortality and Morbidity in Heart Failure: Results from Val-HeFT. Abstract presented at AHA 2002.

⁴ Latini R. Valsartan produces a sustained decrease in plasma aldosterone independent of age, gender or race: Results from Val-HeFT. Abstract presented at ACC 2003.

⁵ Maggioni AP et al. Valsartan reduces the incidence of atrial fibrillation in the patients with heart failure in Val-HeFT. Abstract presented at AHA 2003.