

Karen Sutherland
Novartis Pharma Communications
+41 61 324 7143 (direct)
+41 79 593 1085 (mobile)
karen.sutherland@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

Diovan® receives EU approval for the treatment of heart attack survivors

Leading antihypertensive agent Diovan is first in its class to receive approval to treat people after heart attacks; also being evaluated in EU to treat heart failure

Basel, May 9, 2005 — Novartis announced today that it has successfully completed the EU Mutual Recognition Procedure (MRP) in 14 countries for Diovan® (valsartan) for the treatment of heart attack survivors. Diovan, a proven, powerful antihypertensive agent, is now indicated as a potentially life-saving therapy for the more than 750,000 people in the EU who are at risk of a recurrent heart attack or other serious outcomes such as cardiovascular mortality, hospitalization for heart failure, resuscitated cardiac arrest or stroke. Diovan is also being evaluated by EU regulatory authorities for people with heart failure.

“The most widely prescribed ARB globally, Diovan provides a unique range of benefits to patients with cardiovascular disease that is unlike any other agent of its class,” said Joerg Reinhardt, Head of Development, Novartis Pharma AG. “Already trusted as a highly effective and powerful high blood pressure agent, physicians can now prescribe Diovan to help reduce mortality in patients who have suffered a heart attack.”

This approval provides physicians with a proven life-saving treatment for these high-risk patients who have suffered a heart attack. Despite continual improvements, mortality after heart attack is still high. Now, Diovan can help prolong the life of these high-risk heart attack survivors in addition to providing them with excellent blood pressure lowering efficacy. This indication is based on the VALIANT study which demonstrated that Diovan improved survival and reduced cardiovascular events in high risk patients following a heart attack.

High blood pressure is a major risk factor for heart attacks, which remains one of the world’s deadliest conditions. Every year, more than three million people from EU countries suffer a heart attack.^{1,2} One in three will die within a year after surviving a first heart attack,³ and half of all heart attacks are repeat attacks.⁴ While progress has been made in treating heart attacks in the emergency room, people who survive the acute phase of a heart attack are at greatly increased risk for repeat attacks and are in critical need for new treatments given such a high risk of death.

EU approval based on landmark VALIANT trial

The only drug of its kind to receive such an indication, Diovan has now been approved in more than 50 countries to reduce mortality of high-risk patients following a heart attack. The post-heart attack indication for Diovan is based on the positive results of the 14,703 patient trial known as VALIANT (VALsartan In Acute myocardial iNfarcTion) which was one of the largest long-term studies ever conducted in people who have survived a heart attack. VALIANT demonstrated that Diovan preserved the benefit of captopril, which is one essential component of the currently recommended standard of care in these patients, meaning it reduced death to the same degree as the proven treatment. This finding can

translate into a 25% reduction in premature death by Diovan in patients at high risk 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.⁵ VALIANT also showed that Diovan is well-tolerated in post-heart attack patients. Adverse events were generally related to the underlying disease. The percentage of permanent discontinuations due to adverse events was statistically higher in the captopril-treated (7.7%) patients than in the valsartan-treated (5.8%) patients [$p < 0.05$].

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 60 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.

This new indication for Diovan is for the treatment of clinically stable patients with symptomatic heart failure or asymptomatic left ventricular systolic dysfunction after a recent myocardial infarction (heart attack).

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 represents an impressive research commitment across the cardiovascular continuum, involving approximately 50,000 patients. Recently completed Diovan trials include VALUE in high blood pressure patients at risk for cardiovascular complications, VALIANT in post-heart attack patients and Val-HeFT in heart failure patients. 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 "is being evaluated" 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>.

#

Contacts

Karen Sutherland

Novartis Pharma Communications

+41 61 324 7143 (direct)

+41 79 593 1085 (mobile)

karen.sutherland@novartis.com

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

References

¹ World Health Organization, European Health for All Database, Hospital discharges, ischemic heart disease. Available at <http://hfadb.who.dk/hfa/>.

² World Health Organization, International Classification of Diseases, Diseases of the Circulatory System.

³ American Heart Association, Heart Disease and Stroke Statistics – 2004 Update.

⁴ National, Heart, Lung and Blood Institute, National Institutes of Health, Morbidity & Mortality: 2004 Chart Book on Cardiovascular, Lung, and Blood Diseases.

⁵ Pfeffer MA, McMurray JJ et al. Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med. 2003; 349(20):1893-906.