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## **Novartis announces first Phase III Exforge data, shows strong efficacy as new high blood pressure treatment with dual mechanisms of action**

- *Exforge provides strong blood pressure reductions, including up to 43 mmHg in patients with moderate-to-severe high blood pressure*
- *Majority of patients taking Exforge reach recommended blood pressure goal*
- *US and EU submissions completed in first quarter of 2006*

**Basel, May 17, 2006** — The first Phase III data for Exforge<sup>®</sup> (amlodipine besylate/valsartan) showed patients with high blood pressure treated with the investigational medicine experienced strong reductions of blood pressure – some even up to 43 mmHg – with excellent tolerability.

The Exforge data, which were presented at the American Society of Hypertension, Inc., Annual Scientific Meeting and Exposition (ASH 2006) in New York, also showed that the two complementary mechanisms of action helped more than 80% of patients studied reach their recommended blood pressure goals. Exforge was shown to be safe and well tolerated in the overall clinical trial program involving 5,000 patients.

Exforge is the first high blood pressure medication to combine the most commonly prescribed branded high blood pressure medicines in their respective classes – the calcium channel blocker (CCB) amlodipine besylate and the angiotensin receptor blocker (ARB) valsartan. Submissions for US and EU approval were completed earlier in 2006.

“Many patients need three or more medicines to control their high blood pressure, which is considered the world’s leading killer. Exforge has been shown to be a highly effective and well tolerated blood pressure-lowering agent in a broad range of patients, particularly those who have the most severe high blood pressure and are among the most challenging to treat,” said Dr. James Shannon, MD, Head of Development at Novartis Pharma AG.

Exforge has the potential to be an optimal way to use amlodipine due to a lower incidence of peripheral edema (fluid retention) in patients taking Exforge compared to those taking amlodipine alone. The single-tablet combination also provides the additional efficacy and potential end-organ protection of valsartan, the active ingredient in Diovan<sup>®</sup>.

### **Up to 43 mmHg systolic blood pressure drop in most severe patients**

In the Phase III study<sup>1</sup>, high blood pressure patients (considered to have diastolic blood pressure of 110 mmHg or more but less than 120 mmHg) who were treated with Exforge experienced an average drop of 35.8 mmHg in systolic blood pressure compared to 31.8 mmHg with the combination of the ACE-inhibitor lisinopril and the diuretic hydrochlorothiazide (HCTZ).

Although the study was primarily designed to evaluate the overall safety profile of amlodipine besylate/valsartan, patients with systolic blood pressures of at least 180 mmHg and treated with Exforge achieved an average reduction of 43.0 mmHg compared to 31.2 mmHg with the lisinopril/HCTZ combination.

The results also showed that 80% of patients treated with Exforge for six weeks reached the recommended goal of mean sitting diastolic blood pressure of less than 90 mmHg.

“Reductions in average blood pressure ranging from 35 mmHg to 43 mmHg were significant with amlodipine besylate/valsartan,” said Dr. Don Poldermans, MD, of the Erasmus Medisch Centrum in the Netherlands. “We were particularly impressed by the drug’s efficacy in patients having a systolic blood pressure over 180 mmHg. These findings are important in patients with uncontrolled hypertension since every decrease of 20/10 mmHg in blood pressure halves the risk of cardiovascular events.”

### **About high blood pressure**

High blood pressure – and its consequences – is the world’s No. 1 killer and is estimated by the American Heart Association to affect one in four adults – around one billion people globally. Despite extensive use of current therapies, about 70% of all people with high blood pressure do not reach target blood pressure levels. Many people require three or more medicines to control their blood pressure. Meanwhile, many existing treatments fail to provide sustained 24-hour blood pressure control, particularly during the early morning hours.

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as “has the potential” or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Exforge, or potential future revenue from Exforge. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that any current or future regulatory filings will satisfy the FDA’s or other health authorities’ requirements, that Exforge will be approved for any indications in any market, that Exforge will be brought to market in the US or in any other country, nor that it will reach any particular sales levels. In particular, management’s expectations regarding the approval and commercialization of Exforge could be affected by, among other things, additional analysis of 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; increased government, industry, and general public pricing pressures; and other risks and factors referred to in Novartis AG’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 offering medicines to protect health, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group’s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **Reference**

1. Comparative safety and blood pressure (BP)-lowering efficacy of a combination of amlodipine + valsartan and lisinopril + hydrochlorothiazide in patients with stage 2 hypertension; ASH 2006

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