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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • ME DIENMITTEILUNG**

## **Novartis seeks EU approval for Exforge<sup>®</sup>, a powerful combination of two leading blood pressure medicines in a convenient once-daily tablet**

- *Exforge a combination of amlodipine and valsartan – two of the world’s leading blood-pressure-lowering medicines*
- *Addresses significant unmet need for new combination therapies to help seven out of ten people who are not reaching their treatment goals*
- *Potential for best-in-class efficacy based on clinical data showing significant drop in systolic blood pressure*

**Basel, March 3, 2006**—Novartis has submitted for European approval the new treatment Exforge<sup>®</sup> (amlodipine and valsartan) to help people with high blood pressure – the world’s most common killer estimated to affect at least 25% of all adults<sup>1</sup> – by combining two of the leading blood pressure-lowering medicines in one tablet.

Exforge, a combination of the calcium channel blocker amlodipine and the angiotensin receptor blocker valsartan, has been shown in clinical trials involving more than 5,000 patients to provide powerful blood pressure control with excellent safety and tolerability.<sup>2</sup>

Exforge is expected to help patients who struggle with the inconvenience of multiple medications while trying to reach their blood pressure goals. Significant reductions in both systolic and diastolic blood pressure were observed during the clinical trials, which also showed a lower incidence of peripheral edema (fluid retention) versus the use of amlodipine as a monotherapy<sup>2</sup>.

Novartis is seeking approval for Exforge for use in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy, and as replacement therapy for patients taking amlodipine and valsartan as a free combination – i.e. from separate tablets. A range of Exforge doses are planned to be made available following approval to help people with high blood pressure meet their treatment goals. In addition to the European Union, Exforge is on schedule to be submitted in 2006 for approval in the US as well as in other countries.

“About two-thirds of patients currently take two or more drugs to control their blood pressure,” said James Shannon, Head of Development, Novartis Pharma AG. “This can be very problematic since the burden of having to take multiple pills is one of the main contributors to poor compliance. Exforge offers the powerful efficacy of two very potent drugs, achieving significant blood pressure reductions with good tolerability and the convenience of a single pill.”

Data from clinical trials involving Exforge are planned to be released at the American Society of Hypertension meeting in May 2006.

“The combination of these highly efficacious and well-tolerated agents in a convenient single tablet is very exciting for patients and doctors,” said Professor Luis M. Ruilope, Associate Professor of

Internal Medicine, Head of Hypertension Unit, 12 de Octubre Hospital, Madrid, Spain. “The dual mechanism of action is likely to provide patients with greater benefits over either therapy alone and should lead to improved compliance.”

High blood pressure is the world’s most common killer, affecting at least 25% of all adults.<sup>1</sup> Researchers estimate that the disease affects about one billion people globally.<sup>3</sup> High blood pressure affects and damages arteries in the body, which can burden the heart, kidney, brain and other vital organs and blood vessels. Failing to control high blood pressure can cause heart attacks, strokes, heart and kidney failure as well as premature death. An estimated seven out of ten people with high blood pressure fail to reach their blood pressure targets, with many needing multiple agents to maintain their blood pressure goal.<sup>4,5</sup>

This release contains certain forward-looking statements, relating to the Group’s business, which can be identified by the use of forward-looking terminology such as “likely to provide”, “should lead”, “seeking”, “is expected”, “are planned to be made available following approval”, or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Exforge. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Exforge will be approved for any indications in any market, nor that it will reach any particular sales levels. In particular, management's expectations regarding commercialization of Exforge could be affected by, among other things, additional analysis of Exforge 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 the Company's current Form 20-F on file with the U.S. 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 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 91,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **References**

1. Kearney et al *Lancet* 2005; 365: 217-223
2. Data on file
3. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December 2003, p2
4. Brown et al *Journal of Human Hypertension* 2003; 17, 81-86
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