

Exforge® receives positive European Union regulatory opinion supporting approval as effective new treatment for patients with high blood pressure

- *Exforge delivers strong blood pressure reductions, even up to 43 mmHg in patients with moderate-to-severe hypertension*
- *Exforge combines complementary actions of valsartan and amlodipine – two of the most prescribed branded antihypertension medicines – in a single tablet*
- *Clinical trial results show lower incidence of peripheral edema (swelling of the ankles) in Exforge patients compared to those taking amlodipine alone*

Basel, November 17, 2006 – Novartis announced today a positive opinion supporting European Union approval of Exforge® (valsartan/ amlodipine besylate) as a new treatment option for patients with high blood pressure.

The Committee for Medicinal Products for Human Use (CHMP) issued the positive opinion for this investigational compound based on data showing efficacy and tolerability of Exforge for the treatment of high blood pressure in a clinical trial program involving 5,000 patients.

Exforge is the first high blood pressure medication to combine the two most commonly prescribed high blood pressure medicines in their classes – the angiotensin receptor blocker (ARB) valsartan (Diovan®) and the calcium channel blocker (CCB) amlodipine besylate (Norvasc®).

The European Commission generally follows the CHMP's recommendations and is expected to issue a decision within three months. Novartis plans to make Exforge available to patients in Europe in the April 2007. Exforge has also been submitted for US approval earlier this year, and a decision by the US Food and Drug Administration (FDA) is anticipated in the coming months.

“Exforge offers a potential solution to many patients with high blood pressure who currently need two or more medicines to control their illness. This positive opinion for Exforge is highly encouraging since this medicine has been shown to get patients to blood pressure goal with an excellent efficacy and tolerability profile and a reduced pill burden,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

High blood pressure – and its consequences – is the world's No. 1 killer, 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 two or more medicines to control their blood pressure.

More than 80% of Exforge patients studied reached their recommended blood pressure goals, with reductions in blood pressure of up to 43 mmHg in some groups, according to Phase III data¹ presented at the American Society of Hypertension in May 2006. Exforge also showed a lower incidence of peripheral edema (swelling of the ankles) compared to those taking amlodipine alone.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as, “potential solution”, “is expected”, “generally follows”, “plans to”, “is anticipated”, or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Exforge, or potential future revenue from Exforge. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exforge will be approved for any indications in the European Union, the United States or any other market, that Exforge will be brought to market in the EU, the US or in any other country, nor that Exforge 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; our 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.

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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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