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Exforge® receives final US approval as new and powerful treatment option for patients with high blood pressure

- *Exforge offers two of the most prescribed high blood pressure medicines in a convenient single-tablet form^{1,2,3}*
- *Powerful new treatment option for millions in the US with high blood pressure⁴*
- *Nine out of 10 patients reach high blood pressure treatment goal while taking Exforge during clinical trials⁵*

Basel, June 21, 2007 – Exforge®, a single-tablet combination of two of the world’s most prescribed high blood pressure medicines, has been granted final US regulatory approval and is expected to be available soon as an effective treatment option for millions in the US who suffer from high blood pressure^{1,2,3}.

Exforge is the first medicine of its kind to combine the active ingredients of an angiotensin receptor blocker – Diovan® (valsartan) – and a calcium channel blocker – Norvasc®* (amlodipine) – with the convenience of a single, once-daily tablet^{1,2,3}.

“High blood pressure continues to be a major public health issue in the US. Many patients will require multiple medications to achieve blood pressure control,” said Bertram Pitt, MD, FACC, and a Professor of Medicine Emeritus at the University of Michigan School of Medicine Division of Cardiology. “This new treatment offers great efficacy and improved convenience with a single tablet that will simplify treatment for patients.”

The US approval of Exforge was supported by an extensive clinical program involving more than 5,000 patients¹. The US Food and Drug Administration had tentatively approved Exforge in December 2006 and has now granted final approval.

Exforge was approved in January 2007 in the European Union and has already been made available in nine EU countries, including Germany and the UK, with further launches planned. Exforge is also available in Switzerland.

In two placebo-controlled trials, Exforge helped up to nine out of ten patients reach their treatment goal of diastolic blood pressure under 90 mmHg, or more than a 10 mmHg reduction in diastolic blood pressure from baseline levels⁵. Diastolic blood pressure is measured in millimeters of mercury (mmHg) when the heart is at rest between beats.

In two further clinical trials, Exforge demonstrated superior blood pressure lowering efficacy in patients uncontrolled when taking either valsartan or amlodipine alone, the two high blood pressure drugs combined in Exforge¹.

“Exforge continues our strong heritage in treating high blood pressure, in this case bringing together two of the most widely-used medicines in a single pill,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “Aggressively treating high blood pressure is key, so we are excited to be able to provide physicians and patients with this first-of-a-kind combination to help patients reach recommended blood pressure treatment goals.”

Exforge combines the complementary actions of Diovan – which inhibits angiotensin II, a hormone that causes blood vessels to tighten and narrow – and amlodipine, which inhibits the entrance of calcium into the blood vessel walls. Both of these medicines allow blood vessels to relax so that blood can flow more easily^{1,2,3}.

High blood pressure causes damage to the arteries, burdening the heart, kidneys, brain and other vital organs⁶. At present, high blood pressure affects at least 29% of all adults in the U.S. and approximately one billion people suffer from the condition globally^{7,8}. The number of people with high blood pressure is expected to reach about 1.6 billion by 2025⁹.

In the US, Exforge is not indicated for initial high blood pressure therapy. It has been approved for use in high blood pressure patients who have not been controlled through the use of any type of medicine in the angiotensin receptor blocker or calcium channel blocker classes, and for patients who have experienced dose-limiting side effects on either type of medicine. These include amlodipine-induced edema (swelling), dizziness or flushing¹.

In the Exforge clinical trials, adverse events were generally mild and transient in nature. Side effects that occurred more frequently with Exforge than placebo in clinical trials were peripheral edema (fluid retention), nasopharyngitis, upper respiratory tract infections and dizziness¹.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as, “powerful new treatment option”, “expected”, “will”, “planned”, “continues our strong heritage” or similar expressions, or by express or implied discussions regarding 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 reach any particular sales levels. In particular, management’s expectations regarding the approval and commercialization of Exforge in the US or in other markets could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected intellectual property issues involving the expiration of market exclusivity of amlodipine besylate; competition in general; increased government, industry, and general public pricing pressures; unexpected clinical trial results, including additional analysis of clinical data, or new clinical data; our ability to obtain or maintain patent or other proprietary intellectual property protection; 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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* Norvasc is a registered trademark of Pfizer Inc.

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