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Significant blood pressure reductions seen in difficult-to-treat, black patients receiving Exforge®-based therapy¹

- Study sub-group with severe high blood pressure shows largest blood pressure drop to date in an Exforge clinical trial^{2,3,4}
- After only two weeks, Exforge delivered significantly greater reductions in blood pressure than amlodipine alone¹
- 20 mmHg decrease in systolic blood pressure halves risk of death from heart disease or stroke⁵

Basel, May 14, 2008 — New multinational data show that black patients treated with Exforge® experienced a significantly higher reduction in systolic blood pressure than those on amlodipine alone (33 mmHg vs. 27 mmHg, $P < 0.0001$)¹.

In addition, a subgroup of black patients with severe high blood pressure achieved an average systolic blood pressure reduction of 50 mmHg¹ when taking Exforge and, in some cases, additional hydrochlorothiazide (HCT) at the discretion of the investigator. This is the most significant blood pressure drop seen to date in an Exforge clinical trial^{2,3,4}.

Exforge, a combination of the world's leading high blood pressure medicines Diovan® (valsartan) and amlodipine, produced a significant decrease in blood pressure after only two weeks compared to amlodipine alone (25 mmHg vs. 19 mmHg, $P < 0.0001$)¹.

Uncontrolled blood pressure in difficult-to-treat patients can lead to an increased risk of heart attack and stroke⁶. Studies have shown that lowering systolic blood pressure by 20 mmHg can halve the risk of heart attack and stroke⁵.

“The large blood pressure reductions seen in this trial were experienced by severe patients who have the most difficulty getting their blood pressure to healthy levels,” said Dr. John M. Flack, the lead investigator from Wayne State University School of Medicine, Detroit. “These data may have a real impact on helping patients who are most at risk.”

The results, presented today at the American Society of Hypertension (ASH) 23rd Annual Scientific Meeting and Exposition in New Orleans, show that Exforge got patients in a difficult-to-treat group – black patients with systolic blood pressure ≥ 160 mmHg – to healthy blood pressure levels¹.

Black patients are at higher risk of developing high blood pressure than other ethnic groups for reasons that are not fully understood⁷. They are also less likely than white patients to achieve blood pressure control while receiving treatment⁷. Guidelines recommend that combination therapy should be used as first-line treatment in difficult-to-treat patient groups^{6,8}. Exforge is not currently approved as a first-line treatment for high blood pressure.

High blood pressure is a leading risk factor for cardiovascular disease – the world’s number one cause of death⁹. The condition is treatable, yet 70% of people with high blood pressure are not at goal¹⁰.

“With Exforge, we have a treatment that can help many patients achieve healthy blood pressure levels,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “Importantly, Exforge has been shown to be effective across all grades of high blood pressure and to get as many as nine out of 10 patients to goal. In this study, Exforge demonstrated strong blood pressure lowering efficacy in high-risk, more difficult-to-treat patient populations. Exforge provides an important and effective treatment option for physicians.”

The study presented at ASH investigated whether combination therapy with Exforge is an effective choice in difficult-to-treat, black patients with stage 2 high blood pressure – a more severe stage of the disease, with systolic blood pressure between 160 and 200 mmHg¹. Systolic blood pressure, measured when the heart contracts and pumps, is the most important indicator of a person’s risk of cardiovascular events⁶.

The 12-week randomized, double-blind, parallel-group study was carried out among black patients in the US, South America and South Africa. A total of 572 black patients were randomized to receive either Exforge 5-10/160 mg (n=286) or amlodipine 5-10 mg and placebo (n=286). Demographic and baseline clinical characteristics were comparable between groups¹.

The primary endpoint of the study was the change in systolic blood pressure after eight weeks. Results showed that on average, patients treated with Exforge experienced a significantly greater reduction in systolic blood pressure than those on amlodipine alone (33 mmHg vs. 27 mmHg, $P < 0.0001$)¹. After eight weeks, those patients with a systolic blood pressure ≥ 130 mmHg could have open-label HCT added at the investigator’s discretion (Exforge n=146, amlodipine n=183)¹¹.

At study end, the sub-group of patients with systolic blood pressure ≥ 180 mmHg at baseline taking Exforge, and in some cases HCT at the discretion of the investigator, achieved an average systolic blood pressure reduction of 50 mmHg (n=35), compared to an average 41 mmHg reduction in those taking amlodipine with additional HCT at the discretion of the investigator (n=40, $P = 0.047$)¹. Both medications were well tolerated with adverse events being mild, transient and consistent with the class of agents studied¹.

Novartis is focused on improving the lives of the hundreds of millions of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes – both major public health issues.

The core of the Novartis portfolio is its cardiovascular medications for the treatment of high blood pressure and diabetes. These include the world’s most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients improve cardiovascular and metabolic health through effective medicines, programs and an ongoing commitment to research.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “risk”, “can”, “may”, “likely”, “should”, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Exforge or regarding potential future revenues from Exforge. Such forward-looking statements reflect the current views of the Company regarding future events, and involve

known and unknown risks, uncertainties and other factors that may cause actual results with Exforge 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 additional indications or labelling in any market. Nor can there be any guarantee that Exforge will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exforge could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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

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