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## **Rasilez<sup>®1</sup> shows superior efficacy to ACE inhibitor ramipril in head-to-head study involving people with diabetes and high blood pressure<sup>1,2</sup>**

- *Superior systolic blood pressure reductions with Rasilez monotherapy versus ramipril (ACE inhibitor) seen in study<sup>1</sup>*
- *Rasilez shows additive blood pressure reductions when used with ACE inhibitor<sup>1</sup>*
- *Sustained 24-hour blood pressure control with Rasilez when used alone or in combination with the ACE inhibitor ramipril<sup>2</sup>*
- *Direct renin inhibitors expected to become the first new treatment class for high blood pressure in more than 10 years*

**Basel, June 13, 2006** — Newly-released clinical data show that Rasilez<sup>®</sup> (aliskiren), the first orally effective direct renin inhibitor, provided superior reductions in systolic blood pressure over the ACE inhibitor ramipril in people with diabetes and hypertension.<sup>1</sup>

The data, presented today at 16<sup>th</sup> Scientific Meeting of the European Society of Hypertension (ESH) in Madrid, also show that the combination of Rasilez and ramipril improved blood pressure control over the use of either medication alone.

Other information presented at ESH show that Rasilez provided sustained and persistent blood pressure reductions over 24 hours in people with diabetes.<sup>2</sup> Sustained 24-hour control is important because blood pressure often surges during early morning hours.

“It is particularly important for people with both diabetes and high blood pressure to gain control over both of these diseases,” said Dr. James Shannon, MD, Head of Development at Novartis Pharma AG. “These new data demonstrate that using Rasilez in combination with commonly-used hypertension medicines, such as ramipril, can help patients achieve significantly better blood pressure control than with ramipril alone.”

The US submission of Rasilez was completed in April 2006, while the European submission remains on track for the end of 2006.

High blood pressure, and its consequences, is the world’s No. 1 killer, affecting one in four adults – or approximately one billion people globally.<sup>3</sup> The risk of cardiovascular complications is two to four times higher in people with diabetes than those without the disease, so the International Diabetes Federation recommends tight blood pressure control.<sup>4</sup> Despite extensive use of current therapies, about 70% of people with high blood pressure – and nearly 90% with both diabetes and high blood pressure – have not reached their target blood pressure levels.<sup>5,6</sup>

<sup>1</sup> The tradename Rasilez<sup>®</sup> is currently pending regulatory, including FDA, approval

“People with diabetes and high blood pressure need stringent 24-hour blood pressure control,” said Dr. Hans-Henrik Parving, MD, of the Steno Diabetes Center in Denmark. “This study<sup>2</sup> showed that aliskiren enhanced renin system suppression and resulted in greater blood pressure reductions.”

#### **About the trial**

This eight-week study involved 837 people with diabetes and high blood pressure. The results showed that Rasilez alone reduced mean sitting systolic blood pressure (MSSBP) by 14.7 mmHg compared to 12.0 mmHg with ramipril alone. However, adding aliskiren to ramipril lowered MSSBP by 16.6 mmHg, which was significantly more effective than ramipril alone ( $p < 0.005$ ). Also, responder rates – the number of people reaching the goal for mean sitting diastolic blood pressure (MSDBP) – were higher in people receiving aliskiren.<sup>2</sup>

The most common adverse events were cough and headache, whose frequencies were highest in the ramipril group (4.7% and 6.1%, respectively). Cough and headache were less commonly seen when aliskiren was added to ramipril (1.8% and 2.9%, respectively) than with ramipril alone.<sup>2</sup>

Throughout the clinical program, Rasilez – at doses up to 300 mg (within the expected therapeutic dose range) – has consistently shown tolerability similar to placebo. Rasilez has also been well tolerated when used with other common cardiovascular as well as anti-diabetic medicines.

#### **About Rasilez**

If approved, Rasilez, which was developed with Speedel, will represent the first new treatment approach for people with high blood pressure in more than a decade. It acts within the Renin System, which is central to blood pressure regulation. By directly inhibiting the Renin System’s point of activation – renin – Rasilez decreases the system’s activity, as measured by plasma renin activity (PRA).<sup>7</sup>

#### **Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as “expected to become” “can help”, “on track,” “if approved ... will”, or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Rasilez. 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 Rasilez will be approved for sale in any market, or that it will reach any particular sales levels. In particular, management’s expectations regarding the approval and commercialization of Rasilez could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; 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>.

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