

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Rasilez<sup>®†</sup>, the first-in-class direct renin inhibitor, reduces left ventricular hypertrophy, a powerful predictor of heart disease**

- *New ALLAY study shows Rasilez alone reduced left ventricular hypertrophy (LVH) as effectively as current standard treatment<sup>1</sup>*
- *LVH occurs in nearly a third of high blood pressure patients<sup>2</sup> and doubles risk of premature cardiovascular events or death*
- *ALLAY is the latest in a series of studies to show potential of Rasilez in protecting against heart and kidney disease<sup>3,4</sup>*
- *Approved in more than 40 countries, Rasilez provides strong blood pressure reductions that last beyond 24 hours<sup>5</sup>*

Basel, March 31, 2008 — Rasilez<sup>®</sup> (aliskiren), the first-in-class direct renin inhibitor, has shown clinically meaningful reductions in left ventricular hypertrophy, a proven predictor of heart disease, that are comparable to those seen with the current standard-of-care treatment<sup>1</sup>.

Left ventricular hypertrophy (LVH), or abnormal thickening of the heart muscle, often results from high blood pressure<sup>2</sup>. Affecting nearly a third of patients with high blood pressure, LVH decreases the heart's ability to work efficiently and more than doubles a patient's risk of premature cardiovascular events or death<sup>6</sup>.

High blood pressure currently affects approximately one billion people worldwide and causes about 7.1 million deaths each year<sup>7</sup>. The American Heart Association estimates that high blood pressure will cost the US economy \$66.4 billion in 2008<sup>8</sup>.

Late-breaking results were presented today at the American College of Cardiology meeting in Chicago from the ALLAY study, part of the extensive Rasilez outcomes trial program known as ASPIRE HIGHER.

The study showed that Rasilez alone reduced LVH as effectively as the angiotensin receptor blocker (ARB) losartan (-5.4% vs -4.7% respectively) after nine months of therapy<sup>1</sup>, despite patients having very well-controlled baseline blood pressure. With regard to the study's primary endpoint, the combination of both medicines achieved a numerically greater reduction in LVH than losartan alone, but the result was not statistically significant. Alone and in combination, Rasilez was well-tolerated<sup>1</sup>.

“ALLAY is our first proof that direct renin inhibition, and aliskiren in particular, reduces thickening of heart muscle which is a key risk factor for heart disease,” said Dr Scott Solomon, lead investigator of ALLAY and Director of Non-Invasive Cardiology at Brigham

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<sup>†</sup> Rasilez<sup>®</sup> is the trade name for aliskiren throughout the world, except in the US where it is known as Tekturna<sup>®</sup>

and Women's Hospital, Boston, USA. "This is important because it provides doctors and patients with another LVH treatment alternative, while also providing effective blood pressure lowering."

The ALLAY study is the latest trial in the ASPIRE HIGHER program to highlight the organ protection potential of Rasilez, the first new kind of high blood pressure treatment in more than a decade<sup>1</sup>. Other studies, including ALOFT, have highlighted the protective potential of Rasilez against heart and kidney diseases<sup>3,4</sup>.

ALLAY, involving 460 overweight patients with high blood pressure and LVH from eight countries, investigated whether Rasilez reduced LVH as well as losartan, and whether a combination of the two medicines offered further LVH reductions over losartan alone<sup>1</sup>. Patients were randomized to receive Rasilez or losartan alone, or both in combination<sup>1</sup>.

Professor Björn Dahlöf, Associate Professor in the Department of Medicine at Sahlgrenska University Hospital/Ostra, University of Gothenburg, Sweden, said: "We expect some LVH reductions simply by lowering the patient's blood pressure, but because patients in ALLAY had low baseline blood pressures, the degree of reduction with aliskiren was especially impressive."

ASPIRE HIGHER is the largest ongoing cardio-renal outcomes program and involves more than 35,000 patients in 14 trials, including three new mega-trials. ASPIRE HIGHER is studying Rasilez and direct renin inhibition in a variety of kidney and heart diseases, including diabetic kidney disease and heart failure.

Rasilez acts by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure. Rasilez is approved in more than 40 countries and is proven to provide blood pressure reductions that last beyond 24 hours<sup>5</sup>. It was approved in the European Union in August 2007, and in the US in March 2007 under the trade name Tekturna<sup>®</sup>. Tekturna HCT<sup>®</sup>, the first single-dose combination involving Tekturna, was approved in the US in January 2008.

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**

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