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New data show Tekturna HCT[®] is twice as effective at reducing blood pressure than the diuretic HCT alone

- Recently launched in the US, Tekturna HCT is a single-tablet combination of Tekturna^{®*} and the diuretic HCT for the treatment of high blood pressure¹
- Both Tekturna HCT and Tekturna provide effective blood pressure lowering with good tolerability^{1,2,3}
- Tekturna, first-in-class direct renin inhibitor, provides blood pressure reductions that last beyond 24 hours^{2,4}

Basel, May 15, 2008 — New clinical data presented at the American Society of Hypertension (ASH) show that Tekturna HCT[®] 300/25 mg, a single-tablet combination of the direct renin inhibitor Tekturna[®] (aliskiren) and the diuretic hydrochlorothiazide (HCT)¹, is twice as effective at reducing blood pressure compared to HCT 25 mg alone³. High blood pressure is estimated to affect nearly one in four adults worldwide and remains uncontrolled in nearly 70% of people who have this condition in the United States⁵.

Results of the eight-week study showed that treatment with Tekturna HCT 300/25 mg or 150/25 mg once a day reduced systolic and diastolic blood pressure by 16.7/10.7 mmHg and 12.9/8.5 mmHg respectively compared to 7.1/4.8 mmHg ($p < 0.001$)³ in patients with high blood pressure not adequately responding to HCT alone. Tekturna HCT was well tolerated with fewer occurrences of hypokalemia (low potassium levels in the blood) compared to HCT alone³. Tekturna HCT should not be used in patients who have a low urine output or have allergies to sulfa type drugs.

Most patients need two or more medicines to reach their target blood pressure⁵; therefore a single tablet that combines more than one medicine may help make managing blood pressure more convenient³.

“High blood pressure, or hypertension, is a serious global problem and we are clearly in need of treatments to help patients reach their target blood pressure levels,” said Alan Gradman, MD, Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh, USA. “The data show that Tekturna HCT is an effective and convenient treatment option for patients who have high blood pressure and, as a consequence, have a higher risk of heart attack, heart failure and stroke.”

Additional data presented at ASH reconfirm the ability of the first-in-class direct renin inhibitor Tekturna, known as Rasilez[®] outside the US, to provide significant blood pressure reductions that last beyond 24 hours following a missed dose². Tekturna/Rasilez 300 mg effectively lowered blood pressure beyond the 24-hour dosing interval after a missed dose better than either the angiotensin II receptor blocker (ARB) irbesartan 300 mg or angiotensin-converting enzyme (ACE) inhibitor ramipril 10 mg². This is an important

* Tekturna[®] is the US trade name for aliskiren. Aliskiren is known as Rasilez[®] outside the US.

consideration when treating patients with hypertension because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges.

“Tekturna provides effective blood pressure lowering that lasts beyond 24 hours – a critical benefit for patients, especially during the morning hours when blood pressure rises,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “Eighty percent of blood pressure reductions are maintained for four days after the last dose of Tekturna is given.”

New data also presented at ASH included a *post hoc* analysis of a subset of patients with stage 2 high blood pressure. Tekturna/Rasilez (150-300 mg) provided highly effective systolic and diastolic blood pressure reductions greater than 22.3/12.7 mmHg and achieved superior blood pressure control compared to ramipril (5-10 mg). Stage 2 high blood pressure is a more severe stage of the disease where patients have systolic blood pressure at or above 160 mmHg⁶.

Systolic and diastolic blood pressure represent the maximal (when the heart is pumping) and minimal (when the heart is at rest) pressure within the cardiovascular system, respectively. High blood pressure is generally defined as a consistent systolic pressure of 140 mmHg and higher or a diastolic pressure of 90 mmHg and higher⁵.

Tekturna/Rasilez is being studied in the landmark ASPIRE HIGHER clinical trial program to assess the effect of direct renin inhibition in a variety of conditions, including diabetic kidney disease and heart failure. ASPIRE HIGHER is the largest ongoing cardio-renal outcomes program and involves more than 35,000 patients in 14 studies, including three new mega-trials.

Tekturna/Rasilez acts by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure and organ damage. Tekturna/Rasilez is approved in more than 40 countries^{2,4}. Tekturna[®] was approved in the US in March 2007 and also in the European Union in August 2007 under the trade name Rasilez[®]. Tekturna HCT[®], the first single-dose combination involving Tekturna, was approved in the US in January 2008. Tekturna/Rasilez was discovered by Novartis and developed in collaboration with Speedel.

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 “estimated”, “can”, “may”, “risk”, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Tekturna HCT or Tekturna/Rasilez or regarding potential future revenues from Tekturna HCT or Tekturna/Rasilez. 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 these products to be materially different from any future results, performance or achievements expressed or implied by

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Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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Novartis Media Relations

Beatrix Benz

Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 618 7748 (mobile)
beatrix.benz@novartis.com

Navjot Rai

Novartis Pharma Communications
+41 61 324 6498 (direct)
+41 79 777 6400 (mobile)
navjot.rai@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Ruth Metzler-Arnold +41 61 324 9980
Katharina Ambuehl +41 61 324 5316
Pierre-Michel Bringer +41 61 324 1065
John Gilardi +41 61 324 3018
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America Office

Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

Central phone no: +41 61 324 7944
Fax no: +41 61 324 8444
e-mail: investor.relations@novartis.com

Fax no: +1 212 830 2405
e-mail: investor.relations@novartis.com