

# Novartis AG

## In Heart Failure Patients Treated With ACE Inhibitor and/or Beta Blocker, Higher Plasma Renin Activity is Related to Greater Risk of Mortality

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Basel, Switzerland (ots/PRNewswire) -

- New Analysis of Data From landmark 'Valsartan Heart Failure Trial' Adds to Growing Evidence That Plasma Renin Activity (PRA) is Linked to Cardiovascular Outcomes (1-3)

- PRA is a Measure of the Activity of the Renin Angiotensin System (RAS)

- The Only High Blood Pressure Treatment That Blocks the RAS and Lowers PRA by Directly Inhibiting the Activity of Renin is Rasilez(R) (aliskiren)(4,5)

- Potential Long-term Benefits of Rasilez are Being Further Investigated as Part of ASPIRE HIGHER - the Largest Ongoing Cardio-renal Outcomes Program

Data confirm that in heart failure patients being treated with ACE inhibitor and/or beta blocker, higher plasma renin activity still predicts greater risk of mortality(1). PRA is a measure of the activity of the renin angiotensin system (RAS) which, when chronically activated, can lead to increased blood pressure and organ damage.

A new analysis of data from the Val-HeFT (Valsartan Heart Failure Trial) study in 4,291 chronic heart failure patients was presented at the European Society of Cardiology (ESC) Congress in Barcelona. 93% of the patients were on ACE inhibitor while beta blockers were prescribed to 36% of the patients. Patients were stratified according to levels of PRA at study entry and the association of baseline PRA and all cause mortality at the end of the follow-up period was assessed(1).

"This new Val-HeFT analysis shows that although ACE inhibitors and beta blockers improve outcomes in patients with chronic heart failure, there is still a strong relationship between higher levels of PRA and mortality," said Professor Aldo Maggioni of the Italian Association of Hospital Cardiologists Research Center, Florence, Italy.

This latest evidence is in line with previous research linking PRA to increased cardiovascular morbidity and mortality in heart failure patients(2). Investigators from a recently published study of 699 optimally treated patients with heart failure conclude that PRA predicts the occurrence of cardiovascular events(2).

Rasilez(R) (aliskiren) is a direct renin inhibitor (DRI) which inhibits the activity of the enzyme renin resulting in a decrease of PRA, angiotensin I and II(4,5). For the first time there is now a potent RAS blocker available that reduces PRA alone and in combination with other antihypertensives(6).

"Due to its unique mechanism of action of targeting the RAS at the point of activation, Rasilez lowers PRA when used alone or in combination with other high blood pressure medicines," said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. "The PRA findings from the Val-HeFT study will be further examined in our landmark ASPIRE HIGHER program where we are studying the potential of Rasilez to protect the heart and kidney beyond current treatments."

An estimated 20 million people worldwide suffer from heart failure and despite available treatments, the incidence of death from heart failure continues to increase(7). Heart failure develops slowly, often over years, as the heart gradually loses its pumping

ability, working less efficiently and eventually leading to death.

#### About Rasilez/Tekturna

Rasilez/Tekturna, a direct renin inhibitor, is the only drug that works by directly targeting renin to decrease the activity of the RAS4,5. Renin is an enzyme produced by the kidneys that starts a process that narrows blood vessels and when inappropriately activated, may lead to high blood pressure. By inhibiting renin, Rasilez helps blood vessels relax and widen so blood pressure is lowered.

The heart and kidney protection potential of Rasilez, in addition to its blood pressure lowering ability, is currently being investigated further in the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide involving more than 35,000 patients in 14 trials.

Rasilez/Tekturna is approved in over 70 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. In July 2009, Rasilez also received approval in Japan. Tekturna HCT, the first single-pill combination involving Tekturna, was approved in the US in January 2008 for second-line treatment of high blood pressure, and more recently for first-line use. The single-pill combination Rasilez HCT was approved in the European Union in January 2009. Other single-pill combinations with Rasilez are currently in development including a combination with Diovan(R) and a single-pill combination with amlodipine.

#### About Val-HeFT

Val-HeFT (Valsartan Heart Failure Trial) is one of the largest studies ever conducted in heart failure, involving 5,010 heart failure patients. The study has previously demonstrated that Diovan (valsartan) significantly reduced the combined endpoint of morbidity and mortality by 13.2% (p=0.009) and hospitalization for heart failure by 27.5% (p

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