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New data show Tekturna® and Diovan® used together provide additive blood pressure reductions

- *Study results show more patients receiving both Tekturna and Diovan reached target blood pressure goal compared to those taking either agent alone¹*
- *Tekturna, first new type of high blood pressure medicine in more than a decade, works well alone or in combination with other high blood pressure medicines*
- *Tekturna provides significant blood pressure reductions for 24 hours and beyond with placebo-like tolerability*
- *Strong need for new therapies like Tekturna since nearly 70% of patients with high blood pressure still not achieving treatment goals²*

Basel, July 20, 2007 — Results from a new study involving high blood pressure patients taking Tekturna® (aliskiren) and Diovan® (valsartan) were published today in *The Lancet*. The study, presented earlier this year at the American College of Cardiology congress, shows this combination provides patients with greater blood pressure reductions than either medicine alone and demonstrated tolerability comparable to placebo.

Adding Tekturna to Diovan helped more patients reach their target blood pressure. Nearly half (49.3%) of the patients taking both Tekturna and Diovan reached the target blood pressure level of 140/90 mmHg, which is recommended by treatment guidelines. This proportion of patients was significantly more than with either drug alone (37.4% Tekturna, 33.8% Diovan).

“We are encouraged by these results, because they demonstrate the value of complementary mechanisms of action when Tekturna and Diovan are used together,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “Most people need at least two medicines to effectively control their high blood pressure.”

Tekturna and Diovan work in different ways to target the Renin Angiotensin System, one of the body’s key regulators of blood pressure. Tekturna targets renin, an enzyme responsible for triggering a process that can lead to high blood pressure. Diovan, an angiotensin receptor blocker (ARB) and one of the world’s most-prescribed cardiovascular medicines, blocks a hormone later in this system that causes narrowing of blood vessels³.

The study, involving almost 1800 patients, found that even at maximum doses of Tekturna and Diovan, the combination was safe and well-tolerated. A mild and transient increase in serum potassium levels above 5.5 mmol/L was seen in 4.2% of patients taking both Tekturna and Diovan compared to placebo (2.7%). However, there were fewer reports of serum potassium levels above 6.0 mmol/L in patients taking both medicines (0.5%), compared to 1.5% taking placebo, 1.0% taking Tekturna alone and 1.1% taking Diovan alone. While mild increases in serum potassium may be clinically important in rare situations, potentially life-threatening events associated with increases in serum potassium rarely occur unless the serum potassium concentration exceeds 7.0-7.5 mmol/L⁴, levels which were not seen in this study.

Commenting on an editorial in *The Lancet*, which questioned the safety of such a combination, the study's lead investigator Dr Suzanne Oparil, Professor of Medicine at the University of Alabama at Birmingham and President of the American Society of Hypertension said, "In our study, this combination was clearly shown by the data to be no more likely to increase potassium to unhealthy levels than either drug alone or even placebo. Mild increases in potassium are expected with agents that block the Renin Angiotensin System, including ACE inhibitors and angiotensin receptor blockers, the most-commonly used medicines to treat high blood pressure. Physicians have managed these mild increases in potassium very successfully for over 20 years."

The need for new high blood pressure medicines, including using new combinations of medicines, is strong given that studies estimate that this condition may affect nearly one billion people globally and that more than 70% of patients with high blood pressure remain uncontrolled⁵. In fact, many require two or more medications to reach their target blood pressure goal^{2,6}. Uncontrolled high blood pressure can increase the risk of cardiovascular disease, the world's leading cause of death^{6,7}.

Tekturna received approval in the US in March, 2007. Known as Rasilez outside the US, it received a positive CHMP opinion in June, 2007 recommending approval in the EU and was also recently approved in Switzerland.

Tekturna was developed in collaboration with Speedel.

Disclaimer

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