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Tekturna HCT[®], a single-tablet combination of Tekturna[®]* and a diuretic, receives US approval for treatment of high blood pressure

- *Tekturna HCT combines first approved direct renin inhibitor with the diuretic hydrochlorothiazide (HCT) in a single tablet¹*
- *Approved in more than 40 countries, Tekturna used alone lowers blood pressure for 24 hours and beyond^{2,3}*
- *Data show combination of Tekturna and HCT resulted in significant additional blood pressure reductions compared to either drug alone⁴*
- *Many patients not at goal and most require two or more medicines⁵ – single-tablet combinations simplify treatment by reducing number of pills patients take⁶*

Basel, January 21, 2008 — Tekturna HCT[®] (aliskiren and hydrochlorothiazide) has been approved by the US Food and Drug Administration as a single-tablet combination of two high blood pressure medicines – Tekturna[®] (aliskiren), the first new type of high blood pressure medicine in more than a decade, and the diuretic hydrochlorothiazide (HCT)¹.

The two medicines in this single-tablet combination work together to lower blood pressure, with clinical data showing that the combination of Tekturna and HCT offers greater blood pressure reductions than either component alone⁴.

This is the first regulatory approval of a single-tablet combination therapy involving Tekturna, known as Rasilez[®] outside the US, which has been shown to consistently lower blood pressure for 24 hours and beyond^{2,3}. HCT, sometimes called a “water pill”, is one of the most commonly used high blood pressure medicines⁷. Tekturna HCT is approved for patients not controlled by either medicine alone¹.

The efficacy of Tekturna for 24 hours and beyond is important because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges. Tekturna has also been shown to maintain blood pressure reductions for up to four days after the last dose⁸.

“Current guidelines call for aggressive treatment of high blood pressure and many patients are still not controlled,” said Alan Gradman, MD, Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh, USA. “Tekturna HCT offers patients an effective new treatment option with significant blood pressure reductions and improved convenience, by combining the complementary mechanisms of action of the first direct renin inhibitor and a diuretic in one tablet.”

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

High blood pressure is estimated to affect nearly one in four adults worldwide and remains uncontrolled in nearly 70% of people who have this condition⁵. Most patients require two or more medicines to reach their target blood pressure⁵. Single-tablet combinations such as Tekturna HCT simplify high blood pressure management by reducing the number of pills people take daily⁶.

The US approval of Tekturna HCT was based on clinical trials involving more than 2,700 patients treated with Tekturna and HCT¹.

Tekturna works by targeting renin and decreasing the activity of the renin system as measured by plasma renin activity (PRA). By reducing the effects of renin, Tekturna helps blood vessels to widen so blood pressure is lowered. Diuretics work to lower blood pressure by ridding the body of unneeded water and salt, but are also known to increase PRA.

“Most patients need at least two medicines to control their high blood pressure,” said James Shannon, MD, Chief Medical Officer at Novartis Pharma AG. “The rationale for combining a diuretic, which raises plasma renin activity, with Tekturna, which counters this increase, is compelling and unique, and Novartis is very proud to introduce this innovative combination.”

The most common side effects experienced by more patients taking Tekturna HCT than those taking a placebo (or sugar pill) were dizziness, flu-like symptoms, diarrhea, cough and tiredness.

The long-term potential of Tekturna and direct renin inhibition is being studied in an extensive clinical program known as ASPIRE HIGHER, which focuses on the effects of using Tekturna in patients with cardiovascular or kidney disease.

Tekturna was discovered by Novartis and developed in collaboration with Speedel.

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