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Video and Photo: Tekturna HCT®, a Single-tablet Combination of Tekturna®* and a Diuretic, Receives US Approval for Treatment of High Blood Pressure

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- - Tekturna HCT combines first approved direct renin inhibitor with the diuretic hydrochlorothiazide (HCTZ) in a single tablet
- - Data show combination of Tekturna and HCTZ resulted in significant additional blood pressure reductions compared to either drug alone
- - Many treated patients are not at goal and most require two or more medicines - single-tablet combinations simplify treatment by reducing number of pills patients take

EAST HANOVER, N.J., Jan. 21 /PRNewswire/ -- Tekturna HCT® (aliskiren and hydrochlorothiazide) tablets 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 approved direct renin inhibitor, and the diuretic hydrochlorothiazide (HCTZ).

To view the Multimedia News Release, go to: http://www.prnewswire.com/mnr/novartis/31084/

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

This is the first regulatory approval of a single-tablet combination therapy involving Tekturna, known as Rasilez® outside the US. HCT, sometimes called a "water pill", is one of the most commonly-used high blood pressure medicines. Tekturna HCT is approved for patients not controlled by either medicine alone but should not be used before other medications have been tried first.

"Current guidelines call for aggressive treatment of high blood pressure because approximately 40% of treated patients are still not controlled," said Alan Gradman, MD, Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh, PA. "Tekturna HCT offers patients an effective new treatment option with significant blood pressure reductions and convenience, by combining the first direct renin inhibitor and a diuretic in one tablet."

High blood pressure is estimated to affect nearly one-in-three adults in the US and remains uncontrolled in nearly 70% of treated and untreated adults. Most patients require two or more medicines to reach their target blood pressures. Single-tablet combinations such as Tekturna HCT simplify high blood pressure management by reducing the number of pills people take daily.

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

In a study to evaluate rebound hypertension, when Tekturna was withdrawn, blood pressure reductions were

maintained for up to four days after the last dose, with blood pressure gradually returning toward baseline.

Tekturna is the only drug that works by targeting renin and decreasing the activity of the renin system, as measured by plasma renin activity (PRA). The reductions in PRA were not dose dependent and did not correlate with blood pressure reductions, and the clinical relevance of these reductions are unknown. 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 Marjorie Gatlin, M.D., Vice President, Cardiovascular and Metabolic Therapeutic Area Head, US Medical. "Novartis is very proud to introduce this innovative combination. Tekturna HCT incorporates the latest direct renin inhibition technology and offers an important new option for patients who need greater blood pressure control."

The most common side effects experienced by patients taking Tekturna HCT included dizziness, flu-like symptoms, diarrhea, cough and tiredness. Other less common side effects include skin rash.

Tekturna HCT will be available at wholesalers in early February 2008 in four strengths as tablets containing Tekturna and hydrochlorothiazide: 150 mg/12.5 mg tablets, 150 mg/25 mg tablets, 300 mg/12.5 mg tablets and 300 mg/25 mg tablets.

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.

For more information about Tekturna HCT call 1-888-NOW-NOVA or visit http://www.tekturnahct.com/.

About Tekturna and Tekturna HCT

TEKTURNA HCT and TEKTURNA are prescription medications for adults used to treat high blood pressure. TEKTURNA HCT is not indicated for initial therapy.

Important Considerations:
WARNING: AVOID USE IN PREGNANCY

When pregnancy is detected, discontinue TEKTURNA or TEKTURNA HCT as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.

Do not take TEKTURNA HCT or TEKTURNA if you are allergic to any of the ingredients in the product you are taking.

Do not take TEKTURNA HCT if you have a history of reduced urine output, or have allergic reactions to certain drugs called sulfonamides. Tell your doctor if you take lithium or cyclosporine or if you have ever had a reaction called angioedema to ACE inhibitor medicine.

In clinical studies, the most common side effect experienced by more patients taking TEKTURNA than patients taking a sugar pill was diarrhea. Other less common reactions to TEKTURNA include cough, also with TEKTURNA and TEKTURNA HCT include skin rash. The most common side effects experienced by patients taking TEKTURNA HCT include dizziness, flu-like symptoms, diarrhea, cough and tiredness.

Disclaimer

The foregoing release contains forward-looking statements in the form of express or implied discussions regarding potential future regulatory filings, approvals or future sales of Tekturna HCT or Tekturna. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Tekturna HCT will be approved for sale in the United States or any other market or that Tekturna will be approved for sale in any market where it has not already been approved, or that Tekturna HCT or Tekturna will reach any particular sales levels. In particular, management's expectations regarding the approval and commercialization of Tekturna HCT or Tekturna could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, gastrointestinal and respiratory areas. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 10,000 associates and operates in over 140 countries around the world. For more information, please visit http://www.novartis.com/.

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

Video: http://www.prnewswire.com/mnr/novartis/31084

SOURCE: Novartis

CONTACT: Heather Rose of Novartis Pharmaceuticals Corporation,
+1-862-778-1414, or mobile, +1-917-859-4086, heather.rose@novartis.com

Web site: http://www.novartis.com/
http://www.tekturnahct.com/

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