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Tekturna[®], first new type of high blood pressure medicine in a decade, provides additional blood pressure reduction when used with Diovan[®]

- *New study results show more patients receiving both Tekturna and Diovan reached target blood pressure goal compared to those taking either agent alone¹*
- *Tekturna approved in the US as first direct renin inhibitor, works by directly targeting an enzyme which triggers a process that can lead to high blood pressure*
- *Tekturna provides significant blood pressure reductions for a full 24 hours and generally well tolerated*
- *Urgent need for new therapies like Tekturna since nearly 70% of patients with high blood pressure still not achieving treatment goals²*

Basel, March 26, 2007 — Results from a new study have shown patients taking two Novartis cardiovascular medicines – the recently US-approved drug Tekturna[®] (aliskiren) and the leading therapy Diovan[®] (valsartan) – experienced greater reductions in blood pressure levels than those using either agent alone¹.

The study also found more patients receiving both Tekturna, which received US approval in March and represents the first type of new high blood pressure medicine in a decade, and Diovan reached their treatment goal compared to either drug alone¹.

Data from this trial involving 1,800 patients – the first large-scale study to assess the benefits of combining these medicines – were presented for the first time at the American College of Cardiology 56th Scientific Session in New Orleans.

Half of the patients in the eight-week trial taking both Tekturna and Diovan saw a reduction in blood pressure to the target of 140/90 mmHg (systolic/diastolic pressure), higher levels than seen in patients taking either of the medicines alone. Failure to properly control high blood pressure, also called hypertension, can increase the risk of heart attacks and strokes.

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.

“These study results are exciting because they suggest the value of different mechanisms of action when Tekturna and Diovan are used together,” said Suzanne Oparil, MD, Director of the Vascular Biology and Hypertension Program and Professor of Medicine at the University of Alabama at Birmingham in Alabama.

“In addition to important blood pressure lowering, the combination of Tekturna and Diovan maintained a tolerability profile similar to that seen with either agent alone,” Dr. Oparil said.

Tekturna received US regulatory approval for treatment of high blood pressure as monotherapy or in combination with other high blood pressure medications. In an extensive clinical trial program involving more than 6,400 patients, Tekturna provided significant blood pressure reductions for a full 24 hours. This once-daily oral therapy is expected to be available by the end of March in US pharmacies as 150 mg and 300 mg tablets.

A second study presented at the meeting compared Tekturna to ramipril, another high blood pressure medicine in a class known as ACE inhibitors. Results showed more patients treated with the Tekturna-based therapy reached their blood pressure goal than patients treated with the ramipril-based therapy (61.4% vs. 53.1% respectively)⁴.

The need for new high blood pressure medicines is urgent given that this condition affects one in four adults globally and more than 70% of these patients 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}.

“We are very encouraged by these results since they show Tekturna and Diovan are effective when used together,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “Through our portfolio of high blood pressure medications, Novartis is committed to providing physicians with a wide range of tools to help patients lower their blood pressure.”

About Tekturna

Tekturna received approval in March 2007 from the US Food and Drug Administration (FDA) for the treatment of high blood pressure as monotherapy or in combination with other high blood pressure medications. The use of Tekturna with maximal doses of ACE inhibitors has not been adequately studied. In September 2006, Tekturna – known as Rasilez[®] outside the US – was submitted to the European Medicines Agency (EMA) for review in the European Union. In clinical trials, the approved doses of Tekturna were generally well tolerated. Tekturna was developed in collaboration with Speedel.

About Diovan

Novartis remains at the forefront of cardiovascular medicine through development of innovative products like Diovan, the most-prescribed member of the ARB class (angiotensin receptor blocker) in the world today. Diovan is available for the treatment of high blood pressure in more than 100 countries, for the treatment of heart attack survivors in more than 70 countries and in more than 90 countries for the treatment of people with heart failure.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as “provides”, “can”, “effective”, “is expected”, or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Tekturna/Rasilez, or potential future sales of Diovan. 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/Rasilez will be approved for sale in any other market, or that Tekturna/Rasilez or Diovan will reach any particular sales levels. In particular, management’s expectations regarding the approval and commercialization of Tekturna/Rasilez or Diovan 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 US 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.

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