

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis receives FDA approval of Tekamlo™, a single-pill combination of aliskiren and amlodipine to treat high blood pressure**

- *Tekamlo combines in a single-pill the only approved direct renin inhibitor, Tekturna®, with the widely prescribed calcium channel blocker, amlodipine<sup>1</sup>*
- *Data showed Tekamlo significantly reduced blood pressure compared to amlodipine or Tekturna alone<sup>1</sup>*
- *Up to 85 percent of patients may need multiple medications to help control their high blood pressure, underscoring the need for effective combination treatments<sup>2,3</sup>*

**Basel, August 27, 2010** – The US Food and Drug Administration (FDA) today approved Tekamlo® (aliskiren and amlodipine) tablets, a single-pill for the treatment of high blood pressure combining the only approved direct renin inhibitor, Tekturna® (aliskiren) with the widely used calcium channel blocker, amlodipine<sup>1</sup>. Tekamlo is approved as initial therapy for patients who are likely to need multiple drugs to achieve their blood pressure goals, and as replacement therapy for patients whose blood pressure is not adequately controlled with either aliskiren or amlodipine alone<sup>1</sup>.

“We welcome the FDA’s decision to approve Tekamlo, as the treatment of high blood pressure remains a challenge for many patients requiring multiple medications to control their condition,” said David Epstein, Division Head of Novartis Pharmaceuticals. “This approval reinforces the commitment of Novartis to cardiovascular research and to developing innovative and effective treatments for patients who have not reached their blood pressure goal.”

The FDA approval of Tekamlo was based on clinical trial data involving more than 5,000 patients with mild-to-moderate high blood pressure. An eight-week, randomized, double-blind, placebo-controlled, multi-factorial study showed that the combination of Tekturna and amlodipine resulted in decreases in systolic/diastolic blood pressure at trough of 14-17/9-11 mmHg, compared to 4-9/3-4 mmHg for Tekturna alone, and 9-14/6-8 mmHg for amlodipine alone<sup>1</sup>.

In two additional double-blind, active-controlled studies of similar design evaluating patients with moderate-to-severe high blood pressure (SBP 160 - 200 mmHg), Tekamlo demonstrated significantly greater reductions in systolic and diastolic blood pressures when compared to amlodipine alone<sup>1</sup>. In one study of 443 Black patients the systolic/diastolic treatment difference between Tekamlo and amlodipine was 5.2/3.8 mmHg at the primary endpoint of eight weeks<sup>1</sup>. In the other study of 484 patients the treatment difference between Tekamlo and amlodipine was 7.1/3.8 mmHg at endpoint<sup>1</sup>.

The single-pill combination Tekamlo works to lower blood pressure in two ways. The Tekturna component targets the activity of the renin angiotensin aldosterone system (RAAS), an important regulator of blood pressure<sup>1</sup>. Tekturna directly binds to and inhibits renin, an enzyme produced by the kidneys that starts a process that can make blood

vessels narrow and lead to high blood pressure<sup>1</sup>. The calcium channel blocker, amlodipine lowers blood pressure by relaxing the blood vessel walls through the inhibition of calcium. Both of these medicines enable blood to flow more easily therefore lowering blood pressure<sup>1</sup>. The blood pressure lowering effects of Tekamlo are largely attained within one to two weeks<sup>1</sup>.

“Single-pill combination therapies provide a convenient treatment option while supporting physicians in addressing the complex needs of patients,” said Alan Gradman, M.D., Professor of Medicine at Temple University School of Medicine. “This new single-pill combination demonstrated greater blood pressure reductions than either drug alone in clinical studies and therefore provides a new option to consider when choosing appropriate high blood pressure therapies.”

It is estimated that about one billion people globally have high blood pressure<sup>4,5</sup>, and many of these remain either untreated or treated but are not at their blood pressure target<sup>6</sup>. High blood pressure can cause damage to the vital organs of the body, including the heart, brain and kidneys<sup>5</sup>. However, if high blood pressure is properly controlled, the incidence of stroke and heart failure can be reduced by almost half, and heart attacks by one quarter<sup>5</sup>.

Tekturna/Rasilez<sup>®</sup> is approved in over 80 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez<sup>®</sup>. In July 2009, Rasilez also received approval in Japan. Tekturna HCT<sup>®</sup>, a single-pill combination of aliskiren and hydrochlorothiazide, was approved in the US in January 2008 for second-line treatment of high blood pressure, and in July 2009 for first-line treatment of high blood pressure. The single-pill combination Rasilez HCT<sup>®</sup> was approved in the European Union in January 2009. In September 2009, Valturna<sup>®</sup>, a single-pill combination of aliskiren and valsartan (Diovan<sup>®</sup>), was approved in the US. Tekamlo<sup>®</sup>, the single-pill combination of aliskiren and amlodipine was submitted for European approval in 2009. Other single-pill combinations with aliskiren are currently in development including a single-pill combination with amlodipine and hydrochlorothiazide.

Novartis has a strong cardiovascular and metabolic portfolio, focusing on innovative treatments for high blood pressure and diabetes. These include Diovan<sup>®</sup> (valsartan), the number one selling blood pressure medication worldwide<sup>7</sup>, Exforge<sup>®</sup> (valsartan/amlodipine), a single-pill combining two leading medicines for high blood pressure; Exforge HCT<sup>®</sup> (amlodipine/valsartan/HCT); and Rasilez<sup>®</sup> (aliskiren), the first and only approved direct renin inhibitor, and two single-pill combinations of Tekturna<sup>®</sup>/Rasilez<sup>®</sup>, Tekturna HCT<sup>®</sup>/Rasilez HCT<sup>®</sup> (aliskiren/HCT) and Valturna<sup>®</sup> (aliskiren/valsartan). For the treatment of type 2 diabetes, these include Galvus<sup>®</sup> (vildagliptin, a DPP-4 inhibitor) and Eucreas<sup>®</sup> (vildagliptin and metformin).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “commitment,” “in development,” or similar expressions, or by express or implied discussions regarding potential future approvals of Tekamlo in additional markets, regarding the potential development of other single-pill combinations with aliskiren, or regarding potential future revenues from Tekamlo, Tekturna/Rasilez or other combination products containing aliskiren. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tekamlo will be approved for sale in any additional markets. Nor can there be any guarantee that Novartis will successfully develop any additional single-pill combination products containing aliskiren. Neither can there be any guarantees that Tekamlo, Tekturna/Rasilez or other combination products containing aliskiren will achieve any particular levels of revenue in the future. In

particular, management's expectations regarding such products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, 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.

### **About Novartis**

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **References**

1. Tekamlo (aliskiren and amlodipine) Tablets DRAFT Prescribing Information. August 2010.
2. Dahlöf B, et al. Cardiovascular Morbidity and Mortality in the Losartan Intervention for Endpoint Reduction in Hypertension Study (LIFE): a Randomised Trial Against Atenolol. *Lancet* 2002;359:995–1003.
3. Pepine CJ, Handberg EM, Cooper-DeHoff RM, et al. A Calcium Antagonist vs. a Non-Calcium Antagonist Hypertension Treatment Strategy for Patients with Coronary Artery Disease. The International Verapamil-Trandolapril Study (INVEST): a Randomized Controlled Trial. *JAMA* 2003;290:2805-2816.
4. Kearney P, et al. Global Burden of Hypertension: Analysis of Worldwide Data. *Lancet* 2005;365:217-23.
5. Chobanian AV, et al. Seventh Report of the Joint National Committee on Prevention, Detection Evaluation and Treatment of High Blood Pressure. *Hypertension* 2003;42:1206-1251.
6. Lloyd-Jones D, Adams R, Brown T, et al. for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2010 update. A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2010;121:e46-e215.
7. IMS Midas Worldwide Sales Data. December 2009.

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