



## News Release

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### **2008 Year-End Review of ONTARGET Trial Results Pritor<sup>®</sup>/Kinzal<sup>®</sup> - The Angiotensin II Blocker of choice**

**Berlin/Athens, October 25, 2008** – While the cardiovascular treatment spectrum has improved significantly over the last decade, cardiovascular disease continues to be a worldwide burden with approximately 17 million deaths each year. Outcome of the landmark studies ONTARGET<sup>®</sup> and the parallel trial TRANSCEND<sup>®</sup> showed that the angiotensin II receptor blocker (ARB) telmisartan (Pritor<sup>®</sup>/Kinzal<sup>®</sup>) could become the treatment option of choice for many physicians to further reduce cardiovascular risk. During the symposium today, named: “Be On Target. For More Life.” conducted by Bayer Schering Pharma, leading experts from the field of cardiovascular disease management discussed the role of Pritor<sup>®</sup>/Kinzal<sup>®</sup> (telmisartan) as a renin angiotensin aldosterone system (RAAS) inhibitor for hypertensive patients and patients at high cardiovascular risk.

“Especially for hypertensive patients with associated risk factors, such as diabetes, previous cardiovascular events and subclinical organ damage, the need for effective 24-hours blood pressure reduction and end-organ protection is crucial,” said Professor Giuseppe Mancia, Professor of Medicine and Chairman of the Department of Clinical Medicine and Prevention of the University of Milan-Bicocca, Italy. “It is important that cardio and vascular protection is provided to high-risk patients for improved patient management and, ultimately, for reduction of cardiovascular events.”

In 2007, the PROTECTION<sup>®</sup> study program\* was presented which was initiated to underline the preventive effect of the long-acting telmisartan in patients with hypertension, type 2 diabetes and early target organ damage. This trial demonstrated that telmisartan may have added renoprotective properties and effective end-organ protection in addition to blood pressure control which was consistently maintained over a 24-hour period. “Telmisartan is a selective peroxisome proliferator-activated

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\* PROTECTION: Programme of Research to show Telmisartan End-organ protection

receptor gamma (*PPAR-γ*) modulator and provides additional metabolic benefits important for hypertensive patients at risk of cardiovascular disease”, explained Dr. Alejandro de la Sierra, Research Director of the Hypertension Unit at the Hospital Clinic, Barcelona, Spain. “Telmisartan has a unique pharmacological profile and could therefore become a preferred choice RAAS inhibitor for hypertensives and patients at high cardiometabolic risk.”

Further, the ONTARGET study results which were presented at the American College of Cardiology (ACC) Annual Scientific Session in Chicago in March 2008, showed for Pritor<sup>®</sup>/Kinzalmono<sup>®</sup> (telmisartan) mono therapy arm of the study the same level of cardio and vascular (CV) protection in high CV risk patients as the current gold standard RAAS inhibitor, the angiotensin converting enzyme (ACE) inhibitor ramipril, but indicating a greater tolerability\*\* and higher treatment compliance. The second part of the ONTARGET program, TRANSCEND<sup>®</sup>, underlined the benefits of ONTARGET. Pritor/Kinzal significantly reduces the risk of death from cardiovascular causes, myocardial infarction, or stroke by 13 percent ( $p < 0.05$ ) in the secondary predefined endpoint. This endpoint was used in former landmark trials, in ACE inhibitor-intolerant high CV risk patients already on best standard care. The primary endpoint (CV death, myocardial infarction (MI), stroke, or heart failure hospitalization) had a tendency which was not significant to occur more often in patients of the control group.

“The evidence from both clinical trials, ONTARGET and TRANSCEND, clearly establishes telmisartan as an excellent treatment option for the broadest cross-section of high-risk cardiovascular patients”, said Professor Roland Asmar, Medical Director of the Cardiovascular Center, Paris, France. “The studies showed that telmisartan is not only efficacious, but also well tolerated and associated with a lower risk of discontinuation and therefore especially a good choice for ACE inhibitor-intolerant patients.”

Professor Hermann Haller, Chairman of the Department of Internal Medicine at the Hannover Medical School, Hannover, Germany, and leader of the roundtable discussion summarized that the latest research has provided physicians with the meaningful resource and clinical evidence to improve the treatment of hypertension

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\*\* More discontinuations in the ramipril group than in the Pritor<sup>®</sup>/Kinzal<sup>®</sup> group were due to  
- angioedema ( $p = 0.01$ )  
- cough ( $p < 0.001$ )

More patients in the Pritor<sup>®</sup>/Kinzal<sup>®</sup> group discontinued because of hypotensive symptoms ( $p < 0.001$ )

and cardiovascular disease. “Telmisartan should be considered as first-line treatment for all hypertensive patients irrespective of their risk profile,” concluded Haller.

### **About ONTARGET<sup>®</sup> and TRANSCEND<sup>®</sup>**

The ONTARGET<sup>®</sup> (***ON**going **T**elmisartan **A**lone and in combination with **R**amipril **G**lobal **E**ndpoint **T**rial*) program is the largest, most ambitious ARB clinical study program ever undertaken and was designed to clarify whether telmisartan, marketed by Bayer as Pritor<sup>®</sup> and Kinzalmono<sup>®</sup>, or ramipril, or a combination of the two, confers blood-pressure-independent cardio protection in high-risk patients whose blood pressure is already controlled. The trial was an academically-led study managed by the trials center at McMaster University, Hamilton, Canada.

The ONTARGET<sup>®</sup> trial program was a large, prospective and comparative clinical trial with a total of 31,546 patients in a network of 730 centers from 40 different countries. It consisted of 2 randomized, double-blind, multicenter international trials: a principal trial, ONTARGET<sup>®</sup>, and a parallel trial, TRANSCEND<sup>®</sup> (***T**elmisartan **R**andomised **A**ssessme**Nt** **S**tudy in **ACEI** i**N**tolerant subjects with cardiovascular **D**isease*).

Including 25,620 patients, the ONTARGET<sup>®</sup> study compared cardiovascular outcomes in patients receiving telmisartan 80mg or ramipril 10mg, and combination therapy with telmisartan 80mg plus ramipril 10mg. The primary composite cardiovascular endpoint of ONTARGET<sup>®</sup> was cardiovascular mortality, non-fatal myocardial infarction, hospitalization for congestive heart failure and non-fatal stroke. Patients included in the study had normal or controlled blood pressure, were aged  $\geq 55$  years, were at high risk of developing a cardiovascular event, and had a history of coronary artery disease, peripheral arterial occlusive disease (PAOD), a cerebrovascular event, or diabetes mellitus with end-organ damage. The observation period lasted up to 6 years.

TRANSCEND<sup>®</sup> included a broad cross-section of cardiovascular high-risk patients intolerant to ACE inhibitors (patients older than 55 years, who have had myocardial infarction, peripheral arterial occlusive disease, stroke or transient ischaemic attacks or suffer from diabetes mellitus and additional risk factors). The primary endpoint was a four-fold composite endpoint of CV death, MI, stroke, and hospitalisation for congestive heart failure (CHF). The main secondary endpoint was a three-fold composite endpoint of CV death, MI, and stroke.

The sponsor of the ONTARGET<sup>®</sup> trial program is Boehringer Ingelheim; co-funders in selected countries are Bayer HealthCare and GlaxoSmithKline.

## **About Telmisartan**

Telmisartan was discovered and developed by Boehringer Ingelheim. The company markets telmisartan in 84 countries around the world, including the United States, Japan and European countries, under the trademarks Micardis<sup>®</sup> and MicardisPlus<sup>®</sup> (in combination with hydrochlorothiazide (HCTZ)). Bayer HealthCare/Bayer Schering Pharma promotes telmisartan under the brand names Pritor<sup>®</sup>, PritorPlus<sup>®</sup> (in combination with HCTZ) and Kinzalmono<sup>®</sup>, Kinzalkomb<sup>®</sup> (in combination with HCTZ) in markets across Europe. Telmisartan is indicated for the treatment of essential hypertension. [www.pritor.com](http://www.pritor.com) / [www.kinzal.com](http://www.kinzal.com) / [www.icmaedu.com](http://www.icmaedu.com)

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## **About Bayer Schering Pharma**

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## **Forward-Looking Statements**

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