



News Release

Pritor[®] and Kinzalmono[®] as protective as current gold standard cardiovascular therapy but offers greater tolerability

Results of ONTARGET[®] trial with 25,620 patients presented at ACC in Chicago

Berlin/Chicago, March 31, 2008 – The results of the landmark ONTARGET[®] trial, which were presented today at the 57th Annual Scientific Sessions of the American College of Cardiology (ACC) in Chicago, prove that telmisartan, the modern angiotensin II receptor blocker (ARB), is as protective as ramipril, the current gold standard, in reducing the risk of cardiovascular death, myocardial infarction, stroke, and hospitalization for congestive heart failure in a broad cross-section of high-risk cardiovascular patients, while offering greater tolerability.¹ Telmisartan, marketed by Bayer under the brand names Pritor[®] and Kinzalmono[®] in Europe, is currently indicated for the treatment of essential hypertension.

“The ONTARGET[®] Trial shows that telmisartan is a well-tolerated treatment in high-risk cardiovascular patients that is as effective as ramipril in preventing heart attacks, stroke, hospitalisations for heart failure and deaths,” said Professor Salim Yusuf, lead investigator of the ONTARGET[®] trial program and Director of the Population Health Research Institute at McMaster University, Hamilton, Canada. “The ONTARGET[®] results have important implications for the management of patients with cardiovascular diseases. We now have a new treatment option for high-risk patients which is effective and better tolerated.”

The study showed that cardiovascular events occurred in 16.66% of patients receiving telmisartan, versus 16.46% of patients receiving ramipril, a widely-used angiotensin converting enzyme inhibitor (ACE). The relative risk (ratio of the probability of the event occurring in the telmisartan group versus the ramipril group) was 1.01, with a 95% confidence interval (CI) of 0.94 – 1.09.

The HOPE² trial, by which ramipril was established as the current gold standard therapy, had shown that ramipril reduces the cardiovascular risk for patients by roughly 20%

compared to placebo. The 25,620 high-risk patients who participated in the ONTARGET[®] trial were already receiving best-practice therapy, including statins, antiplatelet therapy, betablockers and/or other antihypertensives. The addition of telmisartan to this therapy resulted in equal or better protection compared to adding ramipril. Telmisartan can therefore now claim the same effect.

Telmisartan was also shown to be significantly better tolerated than ramipril with respect to typical ACE-inhibitor side effects. Although patients with ACE-inhibitor intolerance had been excluded from this part of the trial, 360 patients in the ramipril treatment arm stopped their treatment because they experienced cough, versus only 93 patients in the telmisartan arm. 25 patients stopped their treatment in the ramipril arm because of angioneurotic edema, compared to only 10 in the telmisartan arm. The ONTARGET[®] data therefore shows that telmisartan is associated with higher treatment compliance. Besides efficacy, tolerability and compliance are important factors to consider as they are crucial for effective long-term treatment in the prevention of serious cardiovascular events.

99.8% of participating patients were monitored in the course of the study years. This makes ONTARGET[®] one of the best-managed landmark trials ever and provides an extremely robust data base that will enable the medical community to answer questions where previously no scientific proof was available.

“Through ONTARGET[®], telmisartan has clearly proven to be as effective as ramipril, the current gold standard, but with greater tolerability. The trial’s results will likely influence a change in the management of cardiovascular disease overall,” reiterated Professor Roland Asmar, Medical Director of the Cardiovascular Institute, Paris, France.

Telmisartan is now the only angiotensin II receptor blocker (ARB) with proven cardio and vascular protective benefits beyond blood pressure reduction in this high-risk population.¹ Until now, only the ACE inhibitor ramipril had shown these protective effects. “The benefits of telmisartan seen in ONTARGET[®] and previous trials may be attributed to the specific pharmacological properties and mode of action, including its long half-life, high volume of distribution, high level of tissue penetration, selective AT₁ blockade, slow rate of dissociation from the receptor, high lipophilicity, and selective PPAR- γ modulation,” said Dr. Rahul Agrawal, Global Clinical Leader Cardiology, Bayer HealthCare.

ONTARGET[®] also studied the value of combining telmisartan with ramipril. The aim here was to answer a key question for the clinical community: does combining an ACE inhibitor and an ARB to achieve dual renin-angiotensin system (RAS) blockade offer better protection than single blockade? The results presented today indicate that combining ramipril and telmisartan achieves no additional protective benefit for the overall patient population.

About ONTARGET[®]

The ONTARGET[®] (*ONgoing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial*) program is the largest, most ambitious ARB clinical study program ever undertaken and was designed to clarify whether telmisartan, marketed by Bayer as Pritor[®] and Kinzalmono[®], or ramipril, or a combination of the two, confers blood-pressure-independent cardio protection in high-risk patients whose blood pressure is well controlled. The trial was an academically-led study managed by the trials center at McMaster University, Hamilton, Canada.

The ONTARGET[®] 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[®], and a parallel trial, TRANSCEND[®] (Telmisartan Randomized Assessment Study in ACEI Intolerant Patients with Cardiovascular Disease). The ONTARGET[®] study, which included 25,620 patients, 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 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 ≥ 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.

The sponsor of the ONTARGET[®] trial program was Boehringer Ingelheim; co-funders in selected countries were 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® and MicardisPlus® (in combination with HCTZ). Bayer HealthCare/Bayer Schering Pharma promotes telmisartan under the brand names Pritor®, PritorPlus® (in combination with HCTZ) and Kinzalmono®, Kinzalkomb® (in combination with HCTZ) in markets across Europe.
www.pritor.com / www.kinzal.com / www.icmaedu.com

About Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.
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References

1 The ONTARGET Investigators. Telmisartan, ramipril, or both in patients at high risk for vascular events. N Eng J Med. published online 31 Mar 2008.

2 Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. The Heart Outcomes Prevention Evaluation Study Investigators. N Engl J Med. 2000;342:145-53.