



Press Release

First Telmisartan Symposium on Malta

Effective 24-hours blood pressure lowering and end-organ protection

Major trial programme with hard endpoints to clarify unanswered questions

Leverkusen – A modern antihypertensive should effectively lower blood pressure over a 24-hours period and protect the organs. Studies and experimental tests have confirmed that the AT₁ receptor blocker telmisartan (Pritor®/Kinzal®) meets these requirements. This was the verdict given by scientific experts at the international symposium held on Malta by Bayer HealthCare entitled “Telmisartan – Exceeding the ARB promise”.

There are marked differences between the drug products in the AT₁ receptor blocker class of substances, stressed Dr. Peter Meredith, University of Glasgow, United Kingdom. Telmisartan has a half-life of around 24 hours, making it the longest-acting AT₁ receptor blocker. In one study, telmisartan (40 – 80 mg) lowered blood pressure more effectively in the last six hours of the dosing interval than valsartan (80 – 160 mg). This factor is extremely significant for patients, as it is in this period of time – the early hours of the morning – that the risk of severe cardiovascular complications such as myocardial infarction is at its highest, said Meredith.

In addition to effectively lowering blood pressure, antihypertensives should also have a positive effect on the numerous risk factors that, together with high blood pressure, ultimately lead to cardiovascular disease and serious complications such as myocardial infarction and stroke. This aspect is particularly significant in regard to health care policy, said Professor Pieter A. van Zwieten, Academic Hospital of Amsterdam University, The Netherlands, given that almost one in four adults worldwide suffers from hypertension. It is estimated that this figure will rise to 29 percent by 2025, which would mean that 1.56 billion adults are affected. Demographic trends, increasing body weights and the spread of diabetes are contributing factors in this development.

Experiments have confirmed that telmisartan does more than just lower blood pressure, said Professor Thomas Unger from Charité hospital, Berlin, Germany. For example, the drug product activates PPAR- γ (peroxisome proliferator-activated receptor- γ), a receptor which is involved in the regulation of glucose and lipid metabolism. Influencing this receptor is an important target in diabetes treatment. In an animal model, telmisartan had a significantly greater lowering effect on blood glucose values, insulin levels and triglyceride levels than the control substance losartan. There is increasing scientific evidence that PPAR- γ activators like

telmisartan can influence atherosclerotic processes via the endothelium. This means that these substances exert anti-inflammatory, anti-oxidative and anti-proliferative effects, said Unger. These additional properties of telmisartan that are unrelated to the AT₁ receptor are significant in the treatment of patients with type 2 diabetes and hypertension. Telmisartan could offer a new therapeutic approach for metabolic syndrome, added Unger, as it may be able to prevent the progression of type 2 diabetes.

These positive effects have also been confirmed in patients. Professor Rainer H. Böger, University of Hamburg, Germany, investigated the effects of telmisartan and nisoldipine on vascular dilatation and insulin sensitivity in a prospective, randomized, single-blind trial with 36 hypertensive patients. They received telmisartan (weeks 1-3: 40 mg once daily, weeks 4-6: 80 mg four times daily), nisoldipine (weeks 1-3: 10 mg four times daily, weeks 4-6: 20 mg four times daily) or a combination of the two (weeks 1-3: T 40 mg plus N 10 mg, weeks 4-6: T 80 mg plus N 10 mg). Telmisartan exerted a significant blood pressure lowering effect and also improved endothelium-dependent vasodilatation, said Böger. These effects were observed regardless of whether the patient received monotherapy or combination therapy. Nisoldipine on its own had no significant effect on these parameters. Telmisartan also lowered the fasting insulin levels, while fasting serum glucose remained unaffected. This indicates that less circulating insulin was required in patients receiving telmisartan to maintain their glucose values at the same level as the nisoldipine group. The patients' insulin sensitivity had improved, said Böger.

One major organ that must be protected in hypertensive patients is the kidney. The TRENDY study showed that the kidney function of patients with type 2 diabetes and high blood pressure is markedly improved following treatment with telmisartan, said Professor Athanase Benetos, University of Nancy, France. Telmisartan also exhibited renoprotective effects in the DETAIL study. Telmisartan should therefore be considered an important drug product for primary treatment of type 2 diabetics with hypertension and early-stage renal damage, concluded Benetos.

Major studies with "hard" clinical endpoints will now be conducted to investigate the effects detected in smaller clinical and experimental trials. A comprehensive trial programme has been set up with the support of Bayer HealthCare. The largest of these is ONTARGET® (Ongoing Telmisartan Alone and in Combination with Ramipril Global Endpoint Trial), which is already under way. The objective of this trial is to finally clarify the previously unanswered question of whether telmisartan can be used to treat cardiovascular complications such as myocardial infarction, stroke, heart failure and diabetes significantly better on its own or in combination with the ACE inhibitor ramipril. A total of approximately 30,000 patients with a high cardiovascular risk will take part in the trial. The findings should be available by 2008. "They will have a direct influence on the therapeutic decisions of millions of high-risk patients worldwide," said Professor Stephen MacMahon, University of Sydney, Australia.

Bayer HealthCare

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