
Press Release

Boehringer Ingelheim affirms safety of telmisartan with an analysis of 50,000 patients

Ingelheim, 14 June 2010 - Telmisartan, an angiotensin receptor blocker, is one of the best researched drugs worldwide. It has been studied in clinical trials in more than 50,000 patients. Its positive safety profile has been confirmed also in a market exposure of 34.5 million patient years. Convincing safety data for patients with a high cardiovascular risk were collected in the three long-term outcome trials ONTARGET, PRoFESS and TRANSCEND which followed some of the patients for up to five years. Following rigorous assessment of the data from these studies it was concluded that there was no association with an increased risk of cancer in the telmisartan arms.

Sipahi et al published a meta-analysis in the June issue of *Lancet Oncology*, claiming that angiotensin receptor blockers (ARBs) used to lower hypertension are associated with a modestly increased risk of new cancer diagnosis. The finding is mainly based on the combination arm of telmisartan and ramipril, an angiotensin converting enzyme (ACE)-inhibitor, and not on the trial arms of each compound separately.

Patient health and safety is the primary concern of Boehringer Ingelheim. The company continually monitors safety data for all medical products. Boehringer Ingelheim's comprehensive internal safety data analysis of primary data contradicts the conclusions about an increased risk of potential malignancies mentioned by Sipahi et al.

All studies¹ with telmisartan included patients with cardiovascular risk factors due to age and comorbidities. Specifically, in ONTARGET, with more than 25,000 patients, no statistically significant difference with respect to malignancies was observed in patients treated with telmisartan vs ramipril. In TRANSCEND, a 6,000 patient trial, the difference did not reach significance either. In the PRoFESS trial, another large-scale trial with

more than 20,000 patients, the telmisartan arm showed fewer cases of malignancies than the placebo arm. Considering the analysis of all three trials an effect of telmisartan on malignancies was not observed.

In ONTARGET, the one treatment arm with a combination of telmisartan and ramipril was associated with a modestly increased risk of malignancies. Consistent with our commitment to transparency, data from ONTARGET, TRANSCEND and PROFESS have all been published and been widely shared with regulatory authorities since 2008. It should be noted that product labelling for telmisartan does not recommend the combination of telmisartan and ACE-inhibitors such as ramipril.

“Our research efforts have centered on the need to protect patients, especially older patients from cardiovascular risks such as myocardial infarction or stroke. Telmisartan fulfills this need. It is the only ARB which has cardiovascular protection in its label and has become a valuable treatment option in the management of hypertension and cardiovascular risk. Doctors and patients appreciate its excellent safety profile. In pre-clinical trials, clinical trials and day-to-day patient exposure with telmisartan, we have not seen any significant finding related to malignancies. Patients should consult with their physicians before making any decision regarding their antihypertensive therapy,” said Prof. Dr Klaus Dugi, Corporate Senior Vice President Medicine at Boehringer Ingelheim.

Peer-reviewed meta-analyses of aggregate published data like Sipahi et al have their appropriate place in scientific research. However, these analyses have well-recognised limitations, such as combining study summaries rather than analyzing individual patient data.

Telmisartan is one of the most studied anti-hypertensives in clinical trials, which have all been made publically available. It is widely used as medication to lower blood pressure and protect patients against severe cardiovascular events such as myocardial infarction and stroke.

Contact:

Boehringer Ingelheim Norway KS

Contact: Head of Nordic Clinical Operations, Dr. Øyvind Arnesen

+47 66 76 13 00

Notes to editors

Specifically, in ONTARGET, no statistically significant difference with respect to malignancies was observed in patients treated with telmisartan vs ramipril (HR 1.05, 95%CI 0.94, 1.16). In TRANSCEND, the difference did not reach significance either (HR 1.17, 95%CI 0.97, 1.41). In the PRoFESS trial the placebo arm showed more cases of malignancies than the telmisartan arm (HR 0.92, 95%CI 0.79, 1.06).*

Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates in 50 countries and 41,500 employees. Since it was founded in 1885, the independent, family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2009, Boehringer Ingelheim posted net sales of 12.7 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

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* Data on file
