Boehringer Ingelheim Affirms Safety of Telmisartan With an Analysis of 50,000 Patients and Strongly Disagrees With the Publication of Sipahi et al in Lancet Oncology June 2010

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RIDGEFIELD, Conn., June 13 /PRNewswire/ -- 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 outcome studies 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 (HR 1.05, 95%CI 0.94, 1.16). In TRANSCEND, a 6,000 patient trial, the differe
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SOURCE [1]

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