



Public Statement on DIOVAN® (Valsartan)

Date: July 2, 2010

Novartis is aware of an article published on Monday, 14 June 2010 in The Lancet Oncology by lead author Dr. Ilke Sipahi. The paper looked at the occurrence of cancers, and cancer-related deaths in patients taking a category of drugs called angiotensin receptor blockers (ARBs).

DIOVAN® (valsartan) is in this ARB category and is indicated to treat patients with high blood pressure, heart failure and patients who have had a heart attack. However, DIOVAN was not included in the two main analyses published in the Lancet Oncology paper and which looked at the risk of overall new cancer and how often new lung, prostate and breast cancers occur in studies involving other ARBs.

A third analysis did include two studies with DIOVAN (as well as studies with other ARBs) and looked at cancer-related deaths. This analysis showed no increase in the risk of dying from cancer for patients taking ARBs. In particular, the analysis showed no increase associated with the risk of dying from cancer while on taking DIOVAN.

The article authors conceded that it is not possible to draw conclusions about the risk of cancer associated with each particular ARB, and that the findings need further investigation.

Novartis believes that all drugs should be studied separately through a robust clinical trial program to fully understand each drug's risks and benefits. DIOVAN has been studied in a clinical trial program involving over 56,000 patients. Results of these studies have been published in scientific journals and that information is available for practicing physicians and healthcare authorities. In addition, DIOVAN has been available to patients for more than 14 years. During this time Novartis has routinely conducted safety reviews. These data have shown no apparent signals of increased incidence of cancer and represent more than 68 million patient-years of exposure to DIOVAN.