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Direct Healthcare Professional Communication on potential risks of cardiovascular and renal adverse events in patients with type 2 diabetes and renal impairment and/or cardiovascular disease treated with aliskiren

Dear Healthcare Professional

Novartis would like to inform you about important new safety information for aliskiren (Rasilez) following interim results from the Aliskiren Trial in Type 2 Diabetes Using Cardio-Renal Endpoints (ALTITUDE). Analyses of these data are ongoing. However, in the meantime as a precautionary measure, the following is advised.

Routine (non-urgent) review is recommended for patients taking Aliskiren-containing medicines[1]

- Aliskiren or aliskiren-containing fixed combination products[1] should not be used in combination with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB) in patients with diabetes, therefore:
- Healthcare professionals should stop aliskiren-containing treatment in patients who are diabetic and also taking an ACE inhibitor or an ARB. Alternative antihypertensive treatment should be considered as necessary.
- Aliskiren-containing products should not be initiated in diabetic patients who are also taking either an ACE inhibitor or ARB.
- Patients should not stop any treatment before discussing with a healthcare professional.

Further information on the safety concern

The ALTITUDE study was conducted in type 2 diabetic patients at high risk of fatal and non-fatal cardiovascular and renal events. In most patients arterial blood pressure was adequately controlled at baseline. Aliskiren 300 mg was given in addition to standard of care, including an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB).

[1] Aliskiren-containing combinations: Rasilez, Riprazo, Sprimeo, Rasilamlo, Rasilez HCT, Riprazo HCT, Sprimeo HCT, Rasitrio.

The 4-year multinational randomised, double-blind, placebo-controlled study was designed to evaluate the potential benefits of aliskiren in reducing the risk of cardiovascular and renal events in more than 8606 patients.

On the basis of preliminary interim analyses, the Data Monitoring Committee concluded that study patients were unlikely to benefit from aliskiren. Furthermore, there was a higher incidence of adverse events related to non-fatal stroke, renal complications, hyperkalaemia and hypotension in this high-risk population. Additional analyses from ALTITUDE are ongoing and updated advice may be issued early in 2012.

The content of this letter has been agreed with the European Medicines Agency and the Irish Medicines Board.

Call for Reporting
Please report any suspected adverse events associated with the use of aliskiren (Rasilez/Rasilez HCT) to Novartis Pharmaceuticals Ireland, the Drug Safety and Epidemiology Desk at 01 2080612 or to the Irish Medicines Board.

Communication Information
Should you have any questions or require additional information regarding the use of aliskiren (Rasilez/Rasilez HCT) please contact Dr. Agron Hasani, Novartis Pharmaceuticals Ireland at 01 2601255.

Dr. Greg Hays
Medical Director, Novartis Ireland