Rasilez (aliskiren), Rasival (aliskiren/valsartan) & Rasilez HCT (aliskiren/hydrochlorothiazide)

- Important Safety Information

On 20 December 2011, the Department of Health (DH) was informed by the Novartis Pharmaceuticals (HK) Ltd. (Novartis) on the early termination of the multinational ALTITUDE study (CSPPI00E2337) which involves 8,606 patients from 36 countries.

The ALTITUDE study was the first randomised, double-blind, placebo-controlled phase III study started in October 2007 to determine whether, in patients with type 2 diabetes and pre-existing disease of heart and circulatory system and/or kidney, aliskiren at a target dose of 300 mg once daily (compared to placebo), on top of conventional treatment including an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), reduce death and disease caused by the heart, circulatory system and the kidney. Please note that the ALTITUDE study is not conducted in Hong Kong.

According to Novartis, the ALTITUDE study is being terminated in accordance with the recommendation made by the independent Data Monitoring Committee (DMC) overseeing the trial. After the seventh interim review of data from the study, the DMC concluded that patients were unlikely to benefit from treatment added on top of standard anti-hypertensives, and identified higher adverse events in patients receiving aliskiren in addition to standard of care in the trial. Specifically, in the trial arm in which aliskiren was added to the standard of care, there was an increased incidence after 18-24 months of non-fatal stroke, renal complications, hyperkalemia and hypotension in this high-risk study population.

In Hong Kong, there are 10 aliskiren-containing products and all of them are prescription-only medicines. The approved indication of these products in Hong Kong is for treatment of essential hypertension. You are reminded that the indication for the reduction of death and disease caused by the heart, circulatory system and the kidney in patients with type 2 diabetes has not been approved in Hong Kong. While the results of the ALTITUDE study are...
being assessed, Novartis will cease promotion of Aliskiren-based products for use in combination with an ACE-inhibitor or ARB, and is reviewing the findings with DMCs of other clinical studies involving aliskiren-based products and combination therapies.

Although at the moment there is no special precautionary measure recommended by overseas regulatory authorities in light of the early termination of the study, doctors should take note of the preliminary findings of the study and are reminded to be cautious when prescribing aliskiren-based products to their patients, in particular for those with type 2 diabetes and renal impairment. Moreover, doctors should assess the benefits and risks of the treatment with aliskiren-based products for individual patients and monitor their clinical conditions closely. The Department of Health will keep vigilant against any updated safety issues related to the drug and will present data to the Registration Committee of the Pharmacy and Poisons Board for review as it becomes available.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.drugoffice.gov.hk at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(K.W. LAU)
for AD(D)