Aliskiren Trial Terminated

A randomized, placebo-controlled trial evaluating the addition of the direct renin inhibitor aliskiren (Tekturna – Novartis) to an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) in 8606 patients with type 2 diabetes and renal impairment (ALTITUDE) was terminated prematurely by the manufacturer because the combined incidence of cardiovascular and renal events was higher in patients who received aliskiren than in those who received placebo.1

Combining two different types of drugs that block the renin angiotensin system in patients at high-risk for cardiovascular and renal events has been studied previously. Use of both the ACE inhibitor ramipril (Altace, and others) and the ARB telmisartan (Micardis) in hypertensive patients with diabetes or vascular disease (ONTARGET) did not improve cardiovascular or renal outcomes compared to use of either drug alone, and patients treated with both drugs had more hypotensive symptoms, syncope and renal dysfunction.2

Aliskiren is available alone (Tekturna) and in fixed-dose combinations with hydrochlorothiazide (Tekturna HCT), the calcium channel blocker amlodipine (Tekamlo), both hydrochlorothiazide and amlodipine (Amturnide) and the ARB valsartan (Valtturna) for treatment of hypertension.3 None of these products has been shown to improve clinical outcomes. Novartis is advising prescribers not to use aliskiren-containing products with an ACE inhibitor or an ARB in patients with diabetes.
