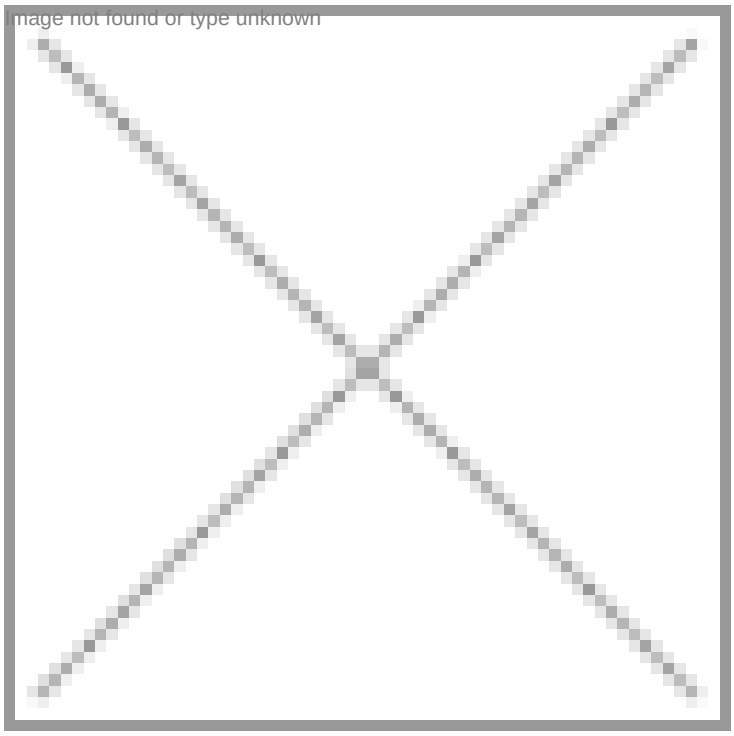
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Takeda gets Japan's approval for hypertension drug NDA

27 March 2014 | Regulatory | By BioSpectrum Bureau



Singapore: Takeda Pharmaceutical has recieved Japan's approval for the New Drug Application (NDA) of Zacras tablets, a fixed-dose combination (FDC) of azilsartan (generic name) and amlodipine besylate hydrochloride, for treatment of hypertension.

Zacras is a tablet taken orally once daily and has two dosage strengths, "Zacras Combination Tablets LD" and "Zacras Combination Tablets HD" which contain 20mg azilsartan / 2.5mg amlodipine, and 20mg amlodipine / 5mg amlodipine respectively.

Discovered by Takeda, azilsartan is a potent and lasting angiotensin II receptor blocker (ARB) that lowers blood pressure by inhibiting the action of angiotensin II, a vasopressor hormone. Amlodipine is a calcium channel blocker (CCB) having a hypotensive action by blocking inward calcium ion channels mainly in vascular smooth-muscle cells, resulting in peripheral arteriolar vasodilation.

The application approval was based on results of phase 3 clinical trials conducted in Japan. A multi-center, randomized, double-blind controlled phase 3 clinical trial with 603 patients with grade I (mild) and II (moderate) hypertension, in which the efficacy and safety of an FDC of azilsartan and amlodipine were compared with monotherapy of either azilsartan or amlodipine.

Given the demand for appropriate blood pressure control that fits the clinical conditions of individual patients, the FDC of azilsartan and amlodipine is a new beneficial hypertension treatment option that is expected to further help control blood pressure for patients.