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Additional indication for Otsuka's Samsca in Japan

September 18, 2013 | News | By BioSpectrum Bureau



Singapore: Japan-based drugmaker Otsuka Pharmaceutical's vasopressin V2 receptor antagonist Samsca 7.5mg tablets has been granted additional indication in Japan for the treatment of fluid retention in patients with hepatic cirrhosis.

Aquaretic agent Samsca was approved in Japan for the treatment of volume overload in patients with liver cirrhosis. Approval of this new indication in Japan is the first such approval in the world, offering a new treatment option to hepatic cirrhosis patients experiencing difficulties or inadequacy with conventional diuretic treatments.

One-third of the estimated 2,70,000 hepatic cirrhosis patients in Japan are said to be facing difficulties in daily living, with swollen hands and legs, and abdominal bloating (ascites). Diuretics are usually prescribed to treat such conditions, but as they cause some patients to experience electrolytic imbalances and declines in kidney function, a new treatment with a different mechanism of action was long desired.

Certain precautions are required when using Samsca, such as initiation or re-initiation only under hospitalization. Patients taking Samsca must have their serum sodium concentration and liver function monitored, both on a frequent basis.

The maximum approved dosage of Samsca is 7.5mg for the treatment of fluid retention in hepatic cirrhosis patients, which is half the dose approved for the treatment of volume overload in patients with heart failure.