

## Daiichi Sankyo kids tumor drug gets Japanese nod

26 March 2013 | Regulatory | By BioSpectrum Bureau



**Singapore:** Daiichi Sankyo received approval for a supplemental new drug application (sNDA) for an additional indication for Topotecin intravenous drip infusion 40 mg and 100 mg (irinotecan hydrochloride hydrate) for pediatric malignant solid tumor from the Japan's Ministry of Health, Labor and Welfare.

A preliminary evaluation was conducted on October 31, 2012, at the meeting of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted, leading Daiichi Sankyo to submit the sNDA for an additional indication of Topotecin in last November.

Chemotherapy is thought to be efficacious for treating pediatric malignant solid tumor. Routine clinical practice involves treatment by a multidrug regimen according to first-line chemotherapy.

The efficacy of irinotecan hydrochloride hydrate has been reported for this indication and it has been recommended as a treatment option in international textbooks and clinical practice guidelines in the last several years. The approval in Japan for the pediatric malignant solid tumor indication is the first approved additional indication for irinotecan hydrochloride hydrate in the world.