

Bayer gets Japan's nod for gastro tumor drug

22 August 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Bayer has received Japan's approval for Stivarga indicated for the treatment of patients suffering from gastrointestinal stromal tumor (GIST) who have progressed following prior systemic cancer therapy.

Stivarga is ready approved in the US for treating patients suffering from metastatic CRC (mCRC), whose disease has progressed even after treatment with standard drugs. Bayer is also seeking EU approval of Stivarga for the treatment of mCRC.

In Jul 2013, Bayer received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the approval of Stivarga in the mCRC indication.