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Bayer colorectal cancer drug gets Japanese nod

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Singapore: Japan's Ministry of Health, Labor and Welfare (MHLW) has approved Bayer HealthCare and Onyx Pharmaceuticals's Stivarga (regorafenib) tablets for the treatment of patients with metastatic colorectal cancer (mCRC).

The approval of Stivarga by the MHLW is based on data from the international multicenter pivotal phase III Correct (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial, which evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with mCRC, whose disease has progressed after approved standard therapies. The study was conducted in 20 sites in Japan.

Stivarga is a Bayer compound developed by Bayer and jointly promoted by Bayer and Onyx in the US. In 2011, Bayer entered into an agreement with Onyx, under which the latter would receive a royalty on all global net sales of Stivarga in oncology.

In September 2012, Stivarga was approved by the US FDA for the treatment of patients with mCRC, who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. It was approved by the US FDA for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate in February 2013.