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Bayer Receives FDA Approval for Stivarga

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The approval of Stivarga in liver cancer marks the third time that this therapy has been granted FDA approval on a priority basis.



Bayer announced that the U.S. Food and Drug Administration (FDA) approved Stivarga® (regorafenib) tablets for the second-line treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib). Stivarga is the first and only treatment to demonstrate significant improvement in overall survival in second-line HCC patients.

Stivarga is an oral inhibitor of multiple kinases involved in normal cellular functioning and in pathological processes such as oncogenesis, tumor angiogenesis, metastasis and tumor immunity.

The approval of Stivarga in liver cancer marks the third time that this therapy has been granted FDA approval on a priority basis. The FDA granted Fast Track designation to Stivarga in this indication, which is an expedited program designed to facilitate development and review of drugs to address unmet medical need in the treatment of a serious or life-threatening condition. The FDA also granted Orphan Drug Designation (ODD) to Stivarga in HCC. The ODD program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders.

Additional regulatory filings for Stivarga in HCC are under review in countries around the world, including the EU, Japan and China. Decisions in the EU and Japan are expected later in this year.