



Stivarga® (regorafenib) – New orphan indication

- On April 27, 2017, the [FDA announced](#) the approval of Bayer's [Stivarga \(regorafenib\)](#), for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with [Nexavar® \(sorafenib\)](#).
- Stivarga is also approved for the treatment of patients with:
 - Metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, [Eloxatin® \(oxaliplatin\)](#)- and [irinotecan](#)-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy
 - Locally advanced, unresectable or metastatic gastrointestinal stromal tumor who have been previously treated with [imatinib mesylate](#) and [Sutent® \(sunitinib malate\)](#).
- According to the [National Cancer Institute](#), there will be approximately 40,710 new cases and 28,920 deaths from liver cancer in 2017 in the U.S. HCC is the most common form of liver cancer.
- The efficacy and safety of Stivarga for the new indication was demonstrated in a double-blind, placebo-controlled study of 573 patients with HCC. The major efficacy outcome measure was overall survival (OS). Additional outcome measures were progression-free survival (PFS) and overall tumor response rate (ORR).
 - The OS was 10.6 months for Stivarga patients vs. 7.8 months for placebo patients (HR = 0.63; 95% CI: 0.50, 0.79; p < 0.0001).
 - The PFS for Stivarga patients was 3.1 months vs. 1.5 months for placebo patients (HR = 0.46; 95% CI: 0.37, 0.56; p < 0.0001).
 - The ORR was 11% for Stivarga patients vs. 4% for placebo patients.
- Stivarga carries a boxed warning for hepatotoxicity.
- The recommended dose of Stivarga for all indications is 160 mg (four 40 mg tablets) taken orally once daily for the first 21 days of each 28-day cycle. Continue treatment until disease progression or unacceptable toxicity.



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