Stivarga® (regorafinib) – New orphan indication

- On April 27, 2017, the FDA announced the approval of Bayer's Stivarga (regorafinib), 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.