Sutent® (sunitinib malate) – New indication

- On November 16, 2017, the FDA announced the approval of Sutent (sunitinib malate) for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy.
    - Sutent is also approved for the treatment of gastrointestinal stromal tumor, advanced RCC, and advanced pancreatic neuroendocrine tumors.
- The approval of Sutent for this new indication was based on a placebo-controlled trial of 615 patients with high risk of recurrent RCC following nephrectomy. The major efficacy outcome measure was disease-free survival (DFS).
    - The median DFS was statistically significantly greater with Sutent vs. placebo [6.8 years vs. 5.6 years, respectively; p = 0.03, HR = 0.76 (95% CI: 0.59, 0.98)].
    - The 5 year DFS rate was 59.3% with Sutent vs. 51.3% with placebo.
    - At the time of the DFS analysis, overall survival data were not mature with 141/615 (23%) patient deaths.
- Sutent carries a boxed warning for hepatotoxicity.
- The recommended dose of Sutent for the adjuvant treatment of RCC is 50 mg orally once daily, 4 weeks on treatment, followed by 2 weeks off for nine 6-week cycles.
- Refer to the Sutent drug label for dosing recommendations for other indications.