FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 19, 2017

DRAFT QUESTIONS

NDA 21938/S-033

Sutent (sunitinib malate)

Applicant: C.P. Pharmaceutical International C.V. represented by Pfizer, Inc.

PROPOSED INDICATION: Adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy

S-TRAC randomized patients at high risk of recurrent renal cell carcinoma following nephrectomy to 1 year of Sutent or placebo. Sutent was administered as 50mg orally 4 weeks on and 2 weeks off and could be reduced to 37.5mg. Patients were followed for disease-free survival with scans every 12 weeks for 3 years and then every 6 months for the duration of follow up. Scans were reviewed by the Investigator and by an Independent Radiology Review Committee. Patients were also followed for overall survival. The results of the primary analysis, disease-free survival as determined by the Independent Radiology Review Committee, are shown below.

	Sutent N = 309	Placebo N = 306
Events	113 (37%)	144 (47%)
Median Disease-free Survival (95% CI)	6.8 years (5.8, NR)	5.6 years (3.8, 6.6)
Hazard Ratio (95% CI), p-value	0.76 (0.59, 0.97), p = 0.03	

Data Cutoff: 4-2016

The safety profile of Sutent in the adjuvant setting is generally similar to that in patients with metastatic renal cell carcinoma. Adverse events during the treatment period resulted in permanent discontinuation in 28% of patients on Sutent and 5% on placebo. Dose interruptions or delays were required in 46% and dose reductions in 35% of patients on Sutent. Grade 3-4 adverse events occurred in 60% and 15% on the Sutent and placebo arms, respectively.

There have been 21% and 24% deaths on the Sutent and placebo arms, respectively. As of January 2017, the estimated hazard ratio for overall survival is 0.92 (95% CI: 0.66, 1.28). A final analysis is expected in 2019.

DRAFT QUESTIONS (cont.)

QUESTION:

1. **VOTE:** Is the benefit-risk profile of Sutent acceptable for the adjuvant treatment of patients at high risk of recurrent renal cell carcinoma following nephrectomy?