

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
December 7, 2011

Draft Questions to the Committee

Session 1: Inlyta (axitinib) tablets

APPLICANT: Pfizer, Inc.

PROPOSED INDICATION: for the treatment of patients with advanced renal cell carcinoma (RCC; kidney cancer)

1. Is the benefit:risk evaluation favorable for axitinib treatment in patients with advanced RCC after failure of a first-line systemic therapy? (VOTE: YES/NO/ABSTAIN)