

Safety and Efficacy of Sorafenib in Japanese Patients with Renal Cell Carcinoma under Daily Medical Practice: Result from the Post-Marketing All-Patient Surveillance with >3200 cases

Introduction and Objective: We report results of the safety and efficacy of sorafenib for the treatment of Japanese patients with RCC under daily medical practice.

Materials and Methods: All Japanese patients with RCC who started treatment with sorafenib between Jan 2008 and Sep 2009 were enrolled in surveillance. Treatment status, metastasis, tumor assessment (at 1, 3, 6, 9 and 12 months), patient outcome, laboratory tests, and adverse events (AE) were monitored for 12 months after starting treatment.

Results: As of the interim cutoff date Jul 2011, 2407 and 2345 patients were evaluable for safety and efficacy, respectively. Patient backgrounds were; male (76%), median age 67, ECOG-PS 0 or 1 (94%), TNM stage IV (98%), prior surgery (83%), prior systemic/cytokine therapy (80/77%), clear cell histology (69%), metastasis (98%) including lung (71%), lung only (26%) and bone (32%), MSKCC risk 1999: low 16%; intermediate 58%; high 5%; unknown 21%. Starting daily dose was 800 mg in 80%. Median duration of therapy and average daily dose were 5.6 months and 525mg, respectively. Discontinuation due to AE occurred in 40%, with hand-foot skin reaction (HFSR) as the most common reason. The most common adverse drug reactions (ADRs) were HFSR (57%), hypertension (34%), diarrhea (19%), alopecia (17%), blood amylase increased (14%), rash (14%), hepatic function abnormal (11%). Timing of onset of ADRs was predominantly within 1 month of starting sorafenib with the exception of diarrhea. The response rate (based on the Japanese Urological Association's rules) was 24%, while the disease control rate including no change was 76%. Median of time to response and duration of response were 53 days and 171 days, respectively. Median PFS was 197 days [95% CI: 188-208 days], and median OS was not reached. OS at 12 months was 69% [95% CI: 66-71%]. Eighty-one percent of patients with lung only metastasis (n=606) and 64% of all other patients (n=1687) were alive at one year.

Conclusions: Sorafenib showed manageable safety profile and favorable efficacy in Japanese patients with advanced RCC under daily medical practice. Final data with approximately 3200 patients will be presented.