SUNNIFORECAST

Sunitinib vs. Nivolumab+Ipilimumab as First line Treatment Of Renal cell Cancer of non-clear cell SubTypes – an international prospective randomized trial

Key Inclusion Criteria

- Metastatic or locally advanced nccRCC: papillary, chromophobe, collecting duct carcinoma (CDC), renal medullary carcinoma (RMC), or translocation tumors and NOS
- Available tumor tissue
- Measurable disease as per RECIST v1.1
- ECOG performance status 0-2
- No prior systemic therapy for RCC
- No active CNS metastases
- No TKI contraindications

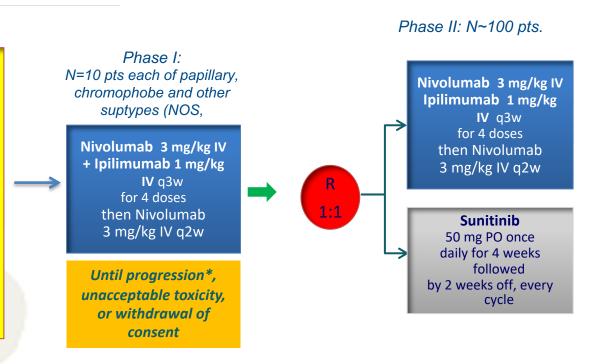
Strata:

- Histological subtype
- •MSKCC score: Risk poor vs. other

Start Date: Q4/2015

Estimated Study Completion Date: Number of Sites ~30 (A, D, F, S, P)

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- Primary Endpoint: Survival rate at 12 mths
- Key Secondary Endpoints:
- Survival rate at 6 and 18 mths
- ORR, TTP, OS, Safety, HR-QoL
- **Exploratory Endpoints:** biomarker e.g.PD-L1 expression of tumor, PD-1 expression of T cell subtypes etc.

