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

Phase I:
N=10 pts each of papillary, chromophobe and other suptypes (NOS,

Nivolumab 3 mg/kg IV + Ipilimumab 1 mg/kg IV q3w for 4 doses then Nivolumab 3 mg/kg IV q2w

Until progression*, unacceptable toxicity, or withdrawal of consent

Phase II: N~100 pts.

R 1:1

Nivolumab 3 mg/kg IV Ipilimumab 1 mg/kg IV q3w for 4 doses then Nivolumab 3 mg/kg IV q2w

Sunitinib 50 mg PO once daily for 4 weeks followed by 2 weeks off, every cycle

- **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.

Start Date: Q4/2015
Estimated Study Completion Date:
Number of Sites ~30 (A, D, F, S, P)
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