First line sunitinib in type I and II papillary renal cell carcinoma (PRCC)
SUPAP - a phase II study of the French Genit-Uriney Group (GETUG) and the Group of Early Phase trials (GEP)

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ABSTRACT #5146

Background
Sunitinib has shown efficacy in metastatic renal cell cancer allowing to approval of anti-angiogenic therapies (bevacizumab, sorafenib) and another anti-angiogenic agent (raf咱nib)

Methods
SUPAP is a single-arm prospective study using a 2-stage design including 21 patients (pts) to evaluate the activity of first line therapy with sunitinib in PRCC. Details of the protocol are available on request.

RESULTS
From 10/07 to 11/08, 5 pts with type I and 23 pts with II PRCC were included. The median age was 58 and 64 yrs respectively. Median of cycles received [range] 4 [1-9]. Patients per cycle 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 27 / 24 / 19 / 17 / 9 / 7 / 5 / 3 / 2

CONCLUSIONS
This study also points out the necessity of an expert review for histological diagnosis. More studies are needed to validate the results.

TREATMENT

- Primary endpoint was ORR, while safety and toxicity analysis was assessed.
- Median of cycles received [range]: 4 [1-9]
- Patients per cycle: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9: 27 / 24 / 19 / 17 / 9 / 7 / 5 / 3 / 2

MATERIAL

- All types
- Adenocarcinoma
- Adenosquamous
- Adenoid cystic
- Clear cell
- Collecting duct
- Chromophobe
- Small cell
- Transitional
- Urothelial

PATOGENESIS

- Histological type was categorized in clear cell carcinoma and papillary carcinoma.
- Primary endpoint: ORR

ENDPOINTS

- Efficacy endpoints: ORR
- To determine time-to-event variables of overall survival, time to disease progression, time to treatment discontinuation.
- Toxicity endpoints: G1-G2 and G3-G4 AEs

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- SUPAP: All partners have contributed to the design of the study, and to the collection and analysis of the data. All authors have read and approved the final version of the manuscript.
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- The SUPAP study was supported by an unrestricted grant from Pfizer France.

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Toxicities were assessed with National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

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