

## Session F. Genitourinary cancer

### F01\* New prognostic factors for second-line targeted therapy (TT) in metastatic renal cell carcinoma (mRCC)

L. Derosa<sup>1</sup>, A. Guida<sup>2</sup>, L. Albiges<sup>2</sup>, C. Massard<sup>2</sup>, Y. Loriot<sup>2</sup>, E. Biasco<sup>1</sup>, A. Farnesi<sup>1</sup>, R. Marconcini<sup>1</sup>, L. Galli<sup>1</sup>, A. Falcone<sup>1</sup>, K. Fizazi<sup>2</sup>, B. Escudier<sup>2</sup>

<sup>1</sup>Azienda Ospedaliero-Universitaria Pisana, Pisa

<sup>2</sup>Institute Gustave Roussy, Villejuif

**Background:** The International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) model has been validated for patients with mRCC in the 2nd line TT setting. This model does not consider time from first to second line therapy, tumor shrinkage during first line and tumor burden before second-line. We sought to investigate these factors in addition to IMDC ones.

**Methods:** Data from patients (pts) treated with TT between January 2005–December 2013 in prospective clinical trials for mRCC were collected from the Gustave Roussy database. All pts who received 2nd-line TT and had available information from 1st line were analyzed. Data collected included known IMDC prognostic factors (anemia,

hypercalcemia, thrombocytosis, neutrophilia, Karnofsky performance status <80, time from diagnosis to treatment <1year) as well as tumor burden (TB), tumor shrinkage (TS), time from first to second line, occurrence of new metastatic sites, number of metastatic sites at second line and histology. Variables with a significant association with overall survival from the start of second line (OS) were estimated by proportional hazard regression and a backward stepwise multivariable analysis identified the independent prognostic factors.

**Results:** From the initial cohort of 316 pts, 222 pts met inclusion criteria and were included in the final analysis. 2nd line treatment was everolimus (27%), sunitinib (24%), sorafenib (22%), axitinib (8%) and other (19%). The median follow-up was 49.4 [range: 2.3 to 97.1] months (mos) and the median OS was 16.8 [95%CI = 12.6, 21.7] mos (79.3% of deaths). By IMDC criteria, mOS was 21.3 mos (95% CI 7.5–49.5) in the good risk group (n = 22), 21.7 mos (15.1–24.9) in the intermediate risk group (n = 142), and 9.3 mos (5.2–12.4) in the poor risk group (n = 58). In univariate analysis, all adverse prognostic factors previously identified by IMDC, except hypercalcemia, TB greater than 9.5 cm, TS greater than 30% and occurrence of new metastatic site were associated with shorter survival. In multivariable analysis, only TS greater than 30% was an independent prognostic factor (p: 0.0004), among new potential prognostic factors.

**Conclusion:** TS during 1st line is an independent prognostic factor for outcome of mRCC in second line. A new prognostic model considering components of the IMDC model with the addition of TS will be presented during the meeting.