Abstract #15408 – Effectiveness and safety of cabozantinib treatment in patients with advanced renal cell carcinoma (RCC) in Spanish and Portuguese real-world practice: Study SOGUG-SPRWEC

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Background

Cabozantinib (cab) was approved for the treatment of metastatic RCC after failure to ≥1 tyrosine kinase inhibitors based on the results of METEOR trial.

Objective

The SOGUG-SPRWEC study investigated the effectiveness and safety of cab in real-world Spanish and Portuguese settings.

Methods

- Observational, ambispective, multicenter study including patients (pts) with advanced RCC who received cab as first and later treatment line.
- Primary objective was progression-free survival (PFS).
- Secondary endpoints included overall survival (OS), overall response rate (ORR) and safety

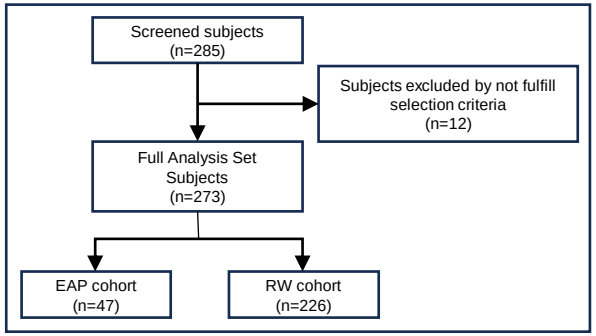

Figure 1. CONSORT flow chart describing patients enrolled in this observational study. EAP: Expanded Access Program; RW: real world.

Study sponsored by SOGUG and funded by Ipsen

Results

- 273 pts were enrolled in this study (Figure 1).
- Median age was 62 years, 75.1% were male (Table 1). 134 (54.5%) pts had received previous immunotherapy. Only 15 (5.5%) pts received cab as first line.

	Total (n=273)
Age, median (min – max)	63 (55.3 – 70.8)
Gender, male, n (%)	205 (75.1%)
Histology, n (%)	
Clear cell RCC	215 (83.3%)
Papillary RCC	31 (12%)
Chromophobe	12 (4.7%)
Nephrectomy, n (%)	221 (81%)
ECOG performance status, n (%)	
0	59 (28.1%)
1	116 (55.2%)
≥2	35 (16.7%)
IMDC risk criteria, n (%)	
Favorable	79 (29.3%)
Intermediate	150 (55.6%)
Poor	41 (15.2%)
Previous tyrosine kinase inhibitor for RCC, n (%)	235 (95.5%)
Previous immunotherapy for RCC, n (%)	134 (54.5%)

Table 1. Baseline clinical characteristics of the enrolled patients.

- Median PFS was 7.66 months (m) (95% CI, 6.6 – 8.7) and median OS was 15.36 m (95% CI, 11.7 – 18.9) (Figure 2).
- ORR was 30% [complete or partial response: 82 (30%), stable disease: 110 (40.3%), progressive disease: 49 (17.9%)] and median duration of response was 8.8 m (Figure 2).

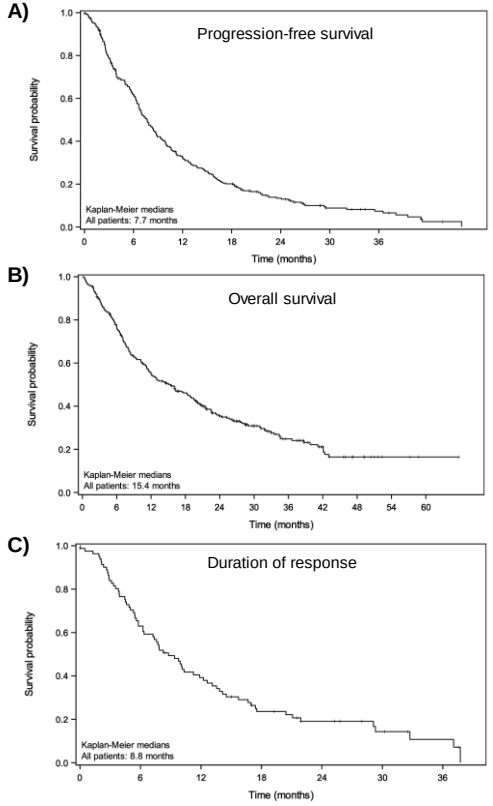

Figure 2. Efficacy endpoints. A) PFS, B) OS and C) Duration of response.

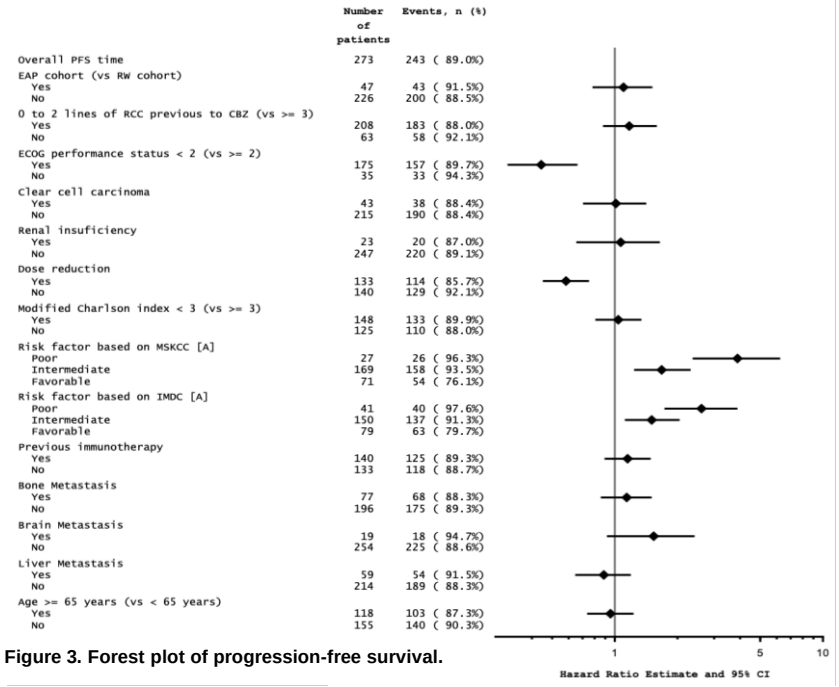

Figure 3. Forest plot of progression-free survival.

- Pts with an ECOG performance status of less than 2 and those who had a dose reduction of cabozantinib exhibited a decreased risk of progression, while patients with poor or intermediate IMDC risk demonstrated an increased risk of progression (Figure 3).

- Previous immunotherapy treatment did not impact PFS (HR 1.152, p=0.28; Figure 3) but was associated with increased ORR (36.4% vs. 23.3%; odds ratio: 1.89; p=0.019), and decreased time to first response (HR: 1.98, p=0.002).

- Most frequent adverse events were diarrhea (37.7% of pts), asthenia (27.8%), anorexia (14.3%), oral mucositis (8.4%), and hypothyroidism (7.7%).

Conclusions

The effectiveness and safety profile of cabozantinib as second and later treatment line for advanced RCC in the real-world setting is similar to that observed in clinical trials.