GU connect

Supported by an Independent Educational Grant from BAYER

MEETING SUMMARY

ESMO 2016 – COPENHAGEN, DENMARK
OCTOBER 7TH TO 11TH 2016

RENAL CELL CARCINOMA (RCC)

BY
DR. LISA DEROSA, INSTITUTE GUSTAVE ROUSSY, VILLEJUIF, FRANCE

GUSTAVE ROUSSY
CANCER CAMPUS GRAND PARIS

UNIVERSITÉ PARIS SUD
FACULTÉ DE MÉDECINE

ÉCOLE DES SCIENCES DU CANCER GUSTAVE ROUSSY

RCC NEWS

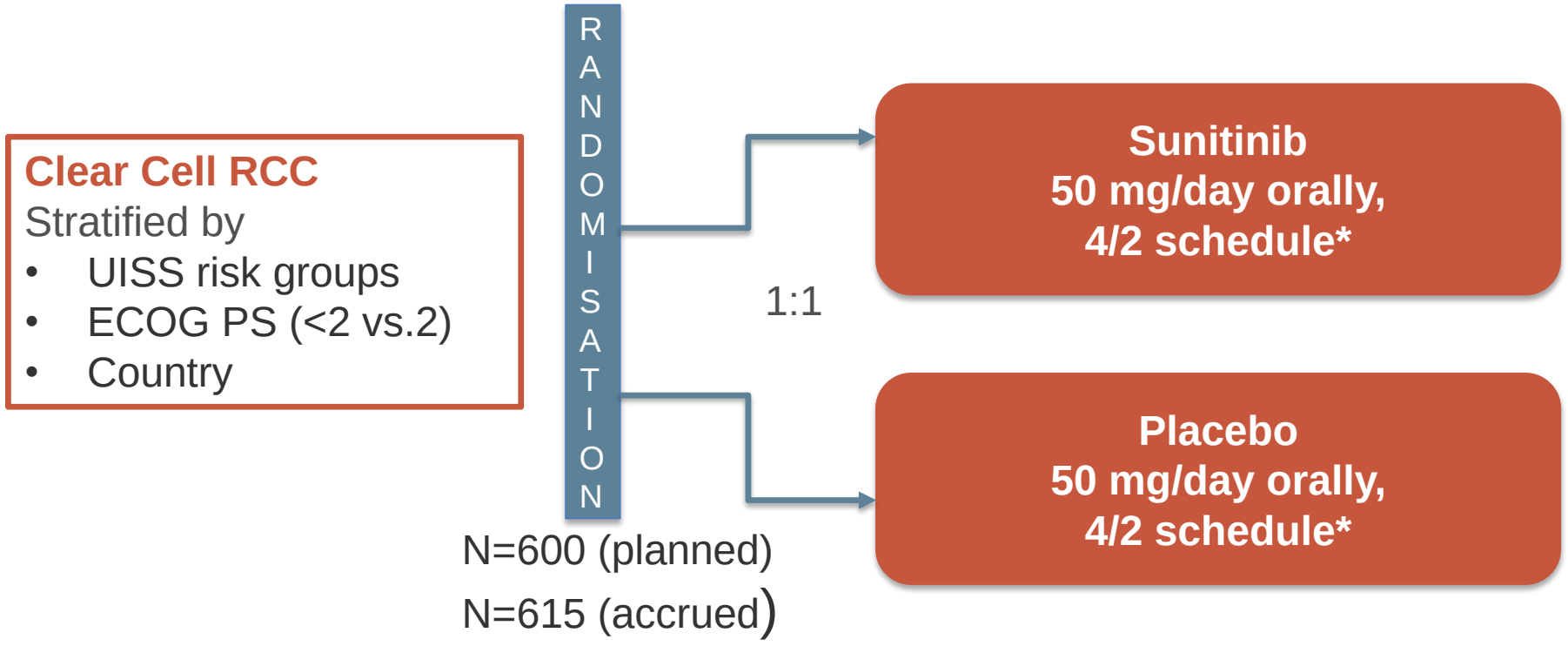
DR. LISA DEROSA, INSTITUTE GUSTAVE ROUSSY, VILLEJUIF, FRANCE

S-TRAC TRIAL

ALAIN RAVAUD, MD, PHD
BORDEAUX UNIVERSITY HOSPITAL FRANCE

PHASE III TRIAL OF SUNITINIB VERSUS PLACEBO AS ADJUVANT TREATMENT FOR HIGH-RISK RCC AFTER NEPHRECTOMY (S-TRAC)

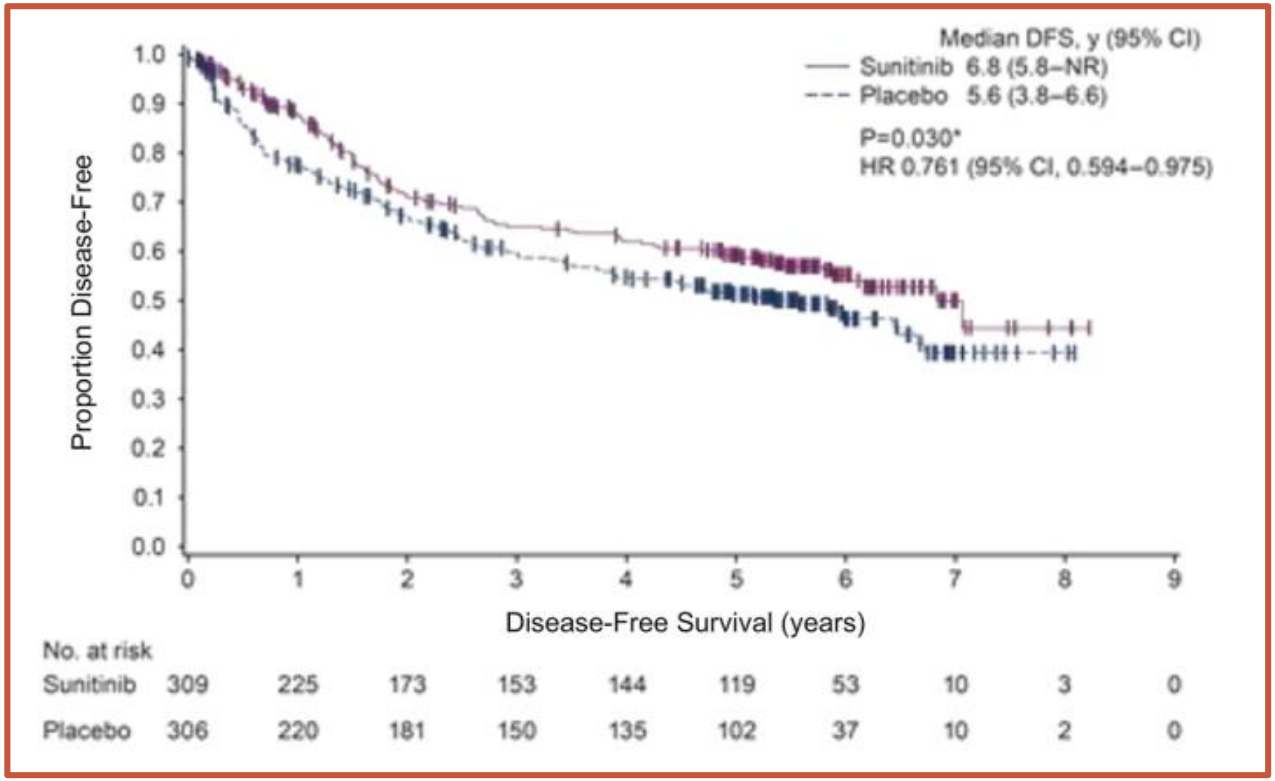
Study Design



*Dose reduction only to 37.5 mg/day allowed

PHASE III TRIAL OF SUNITINIB VERSUS PLACEBO AS ADJUVANT TREATMENT FOR HIGH-RISK RCC AFTER NEPHRECTOMY (S-TRAC)

Disease-Free Survival By Blinded Independent Central Review



*Two-sided P value from log-rank test stratified by UISS high-risk group

PHASE III TRIAL OF SUNITINIB VERSUS PLACEBO AS ADJUVANT TREATMENT FOR HIGH-RISK RCC AFTER NEPHRECTOMY (S-TRAC)

Common Treatment-Emergent Adverse Events*

Adverse Event %	Sunitinib (n=306)			Placebo (n=304)		
	All Grades	Grade 3	Grade 4	All Grades	Grade3	Grade 4
Any adverse event	99.7	48.4	12.1	88.5	15.8	3.6
Diarrhea	56.9	3.9	0	21.4	0.3	0
PPE	50.3	15.0	1.0	10.2	0.3	0
Hypertension	36.9	7.8	0	11.8	1.0	0.3
Fatigue	36.6	4.2	0.7	24.3	1.3	0
Nausea	34.3	2.0	0	13.8	0	0
Dysguesia	33.7	0	0	5.9	0	0
Mucosal inflammation	33.7	4.6	0	8.2	0	0
Dyspepsia	26.8	1.3	0	6.3	0	0
Stomatitis	26.5	1.6	0.7	4.3	0	0
Neutropenia	23.5	7.5	1.0	0.7	0	0
Asthenia	22.5	3.6	0	12.2	0.7	0.3
Hair colour change	22.2	0	0	2.3	0	0
Thrombocytopenia	20.9	4.9	1.3	1.6	0.3	0

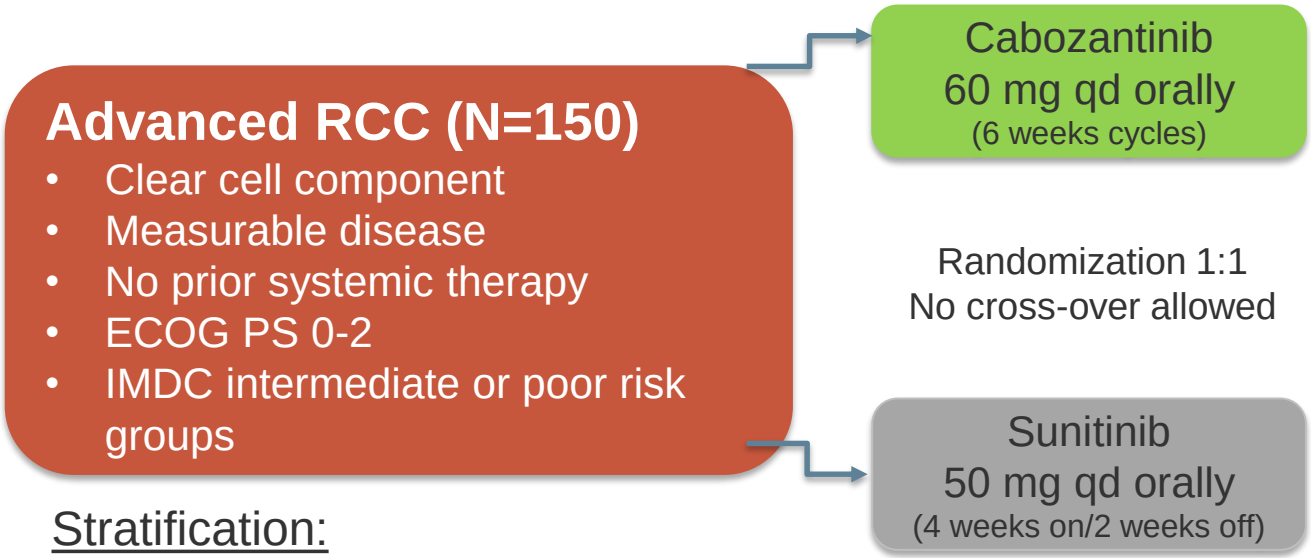
*Experienced by > 20% of patients; Grade 5 events occurred in 5 (1.6%) patients in the sunitinib arm and 5 (1.6%) patients in the placebo arm; no grade 5 adverse events in either arm were considered treatment-related.
PPE, Palmar-palmar erythrodysesthesia syndrome

CABOSUN TRIAL
ALLIANCE A031203 TRIAL

Dr. T. Choueiri
Dana-Farber Cancer Institute, Boston, USA

CABOZANTINIB VERSUS SUNITINIB (CABOSUN) AS INITIAL TARGETED THERAPY FOR PATIENTS WITH MRCC OF POOR AND INTERMEDIATE RISK GROUPS

Study Design



Tumor assessment by RECIST 1.1 every other cycle

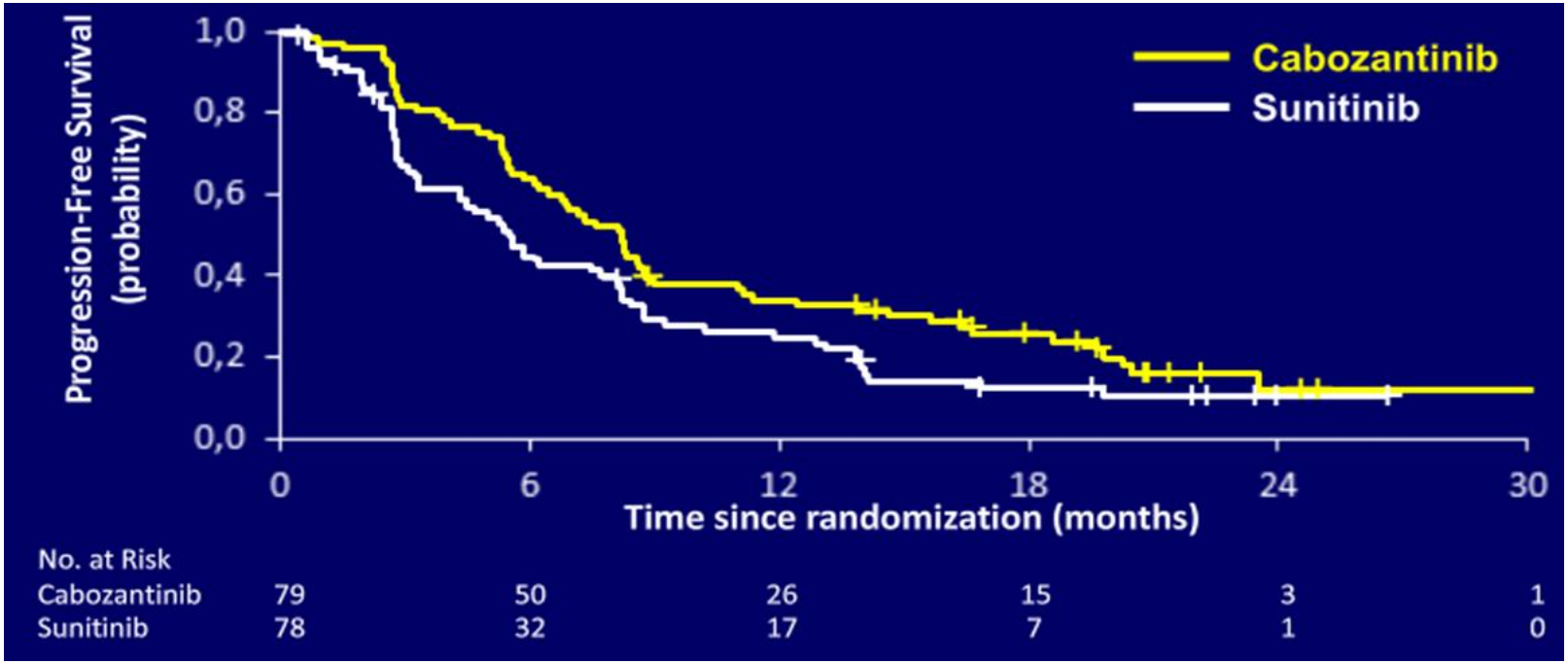
Treatment until disease progression or intolerable toxicity

Stratification:

- IMDC risk group[1]: intermediate, poor
- Bone metastases: yes, no

Presented at the ESMO 2016 Congress, Copenhagen
Heng D et al., J Clin Oncol, 2009

CABOZANTINIB VERSUS SUNITINIB (CABOSUN) AS INITIAL TARGETED THERAPY FOR PATIENTS WITH MRCC OF POOR AND INTERMEDIATE RISK GROUPS



Arm	PFS Events	Median PFS (95% CI), mo	HR (95% CI)*
Cabozantinib	64	8.2 (6.2, 9.0)	0.69 (0.48-0.99)
Sunitinib	61	5.6 (3.4, 8.1)	P-value (one sided) = 0.012

*Adjusted for bone metastases and IMDC risk group

CABOZANTINIB VERSUS SUNITINIB (CABOSUN) AS INITIAL TARGETED THERAPY FOR PATIENTS WITH MRCC OF POOR AND INTERMEDIATE RISK GROUPS

	Cabozantinib (N=78)		Sunitinib (N=72)	
Preferred Term, %	ALL Grades	Grade 3/4	All Grades	Grade 3/4
*Any adverse events**	99	65	99	68
Fatigue	86	6	82	15
Hypertension	81	28	68	22
Diarrhea	73	10	54	11
AST increased	62	3	32	3
ALT increased	55	5	28	0
Anorexia	47	5	32	0
PPE	42	8	33	4
Dysgeusia	41	0	29	0
Thrombocytopenia	40	1	63	11
Oral mucositis	36	5	29	6
Anemia	33	1	46	1
Nausea	32	3	39	4
Weight loss	32	4	17	0
Neutropenia	15	0	35	4
Leukopenia	12	0	35	3

*Events reported in at least 30% of patients in either study group; PPE, palmar-plantar erythrodysesthesia

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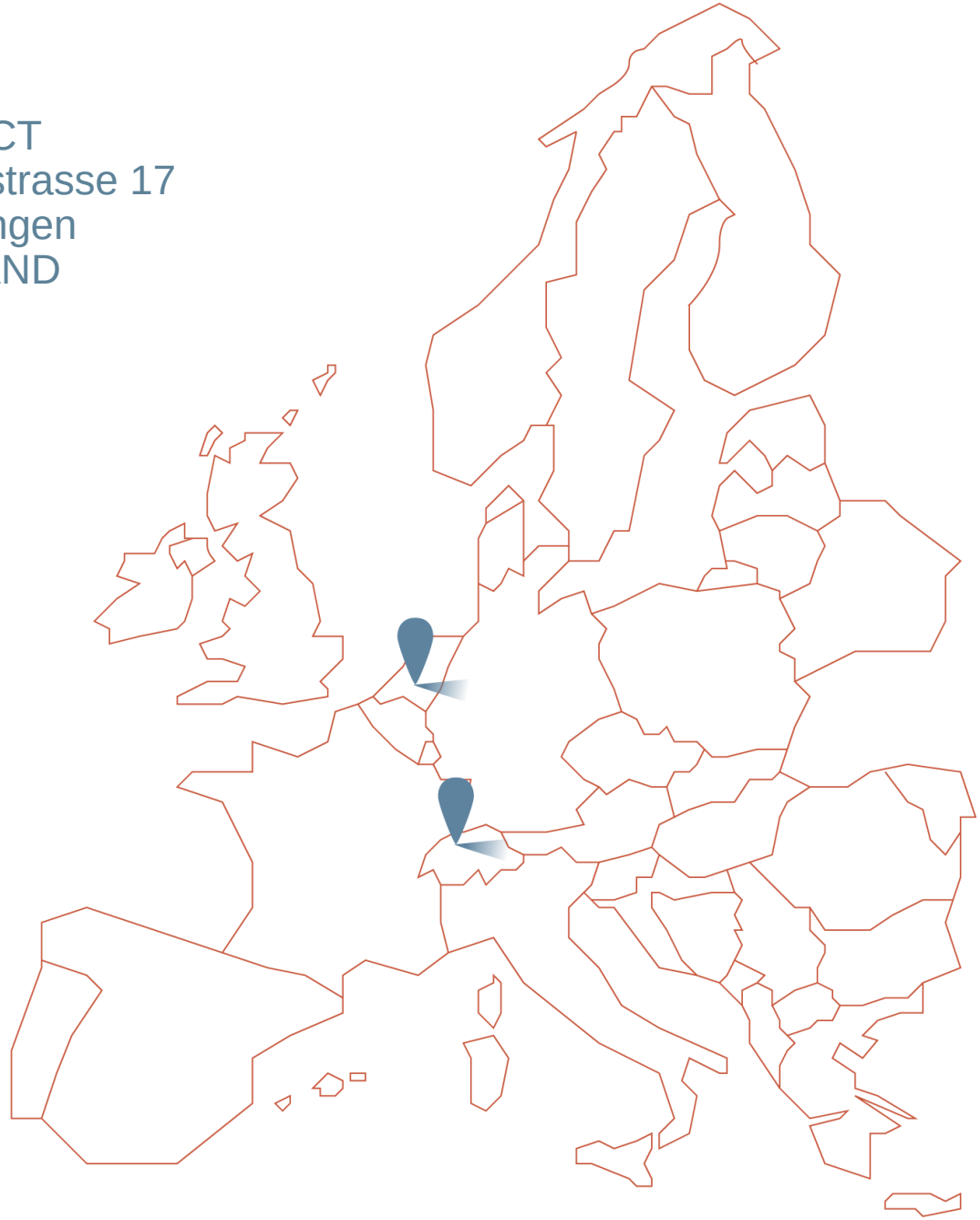

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